

104  
**RISK ASSESSMENT AND COST BENEFIT  
ANALYSIS**

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Risk Assessment and Cost Benefit An...

**HEARINGS**

BEFORE THE

**COMMITTEE ON SCIENCE**

**U.S. HOUSE OF REPRESENTATIVES**

**ONE HUNDRED FOURTH CONGRESS**

**FIRST SESSION**

**JANUARY 31; FEBRUARY 3, 1995**

**[No. 3]**

Printed for the use of the Committee on Science



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# RISK ASSESSMENT AND COST BENEFIT ANALYSIS

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# RISK ASSESSMENT AND COST BENEFIT ANALYSIS

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TUESDAY, JANUARY 31, 1995

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON SCIENCE,  
*Washington, D.C.*

The committee met, pursuant to call, at 10:30 a.m. in Room 2318, Rayburn House Office Building, Hon. Robert S. Walker [chairman of the committee] presiding.

The CHAIRMAN. This meeting of the Science Committee is called to order.

I do have a couple of items that I would like to get out of the way in terms of business initially and then move to opening statements.

I would remind the members that what we intend to do is take account of those members who were in the room as the gavel came down in terms of determining order of questioning the witnesses later on, that people now in the room will be regarded on an equal footing based upon the seniority, and the people who join us later on will be recognized in the order in which they come into the room.

First to just complete some business of the committee, I would move that the subcommittee chairmen recommended by the Republican Caucus be confirmed by the committee. Is there any objection?

Hearing none, so ordered.

I move the subcommittee memberships recommended by the Committee Republican Caucus and the Democratic Caucus be confirmed by the committee.

Any question or discussion?

If not, without objection, so ordered, and I move the committee approve the statutory staff for the 104th Congress which is listed before you.

[The list follows:]

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The CHAIRMAN. Any discussion or questions on that?

If not, without objection, so ordered.

I also would announce the vice chairmen of the full committee and subcommittees that have recently been appointed. Vern Ehlers from Michigan will be the vice chairman of the full committee. Dave Weldon of Florida will be vice chairman of the Space Subcommittee. Lindsey Graham of South Carolina will be vice chairman of the Energy and Environment Subcommittee. Zach Wamp of Tennessee will be vice chairman of the Basic Research Subcommittee. Ken Calvert of California will be vice chairman of the Technology Subcommittee.

Today the committee is meeting to receive testimony regarding title III of H.R. 9, the Job Creation and Wage Enhancement Act of 1995, which has been referred to this committee as the committee of primary jurisdiction. Title III would create a system of risk assessment and cost-benefit analysis for all Federal agencies which issue regulations designed to protect human health, safety, and environment.

Last year this committee held extensive hearings on risk assessment legislation and marked up H.R. 4306, the Risk Assessment Improvement Act of 1994. Although that legislation applied only to the Environmental Protection Agency, many of the principles of risk characterization and communication have been incorporated into subtitle A of the legislation before us. Also for our consideration is a second subtitle which mandates extensive cost-benefit analysis of regulations designed to protect human health, safety, and the environment.

The third element of title III would establish a systematic program for peer review of risk and economic assessments used by each agency. The purpose of this subtitle is to have an independent evaluation of the quality of science used to support implementing regulations. Today we will hear from a panel of witnesses from the private sector who I believe can give us a broad range of opinion as to the way in which the legislation before us would be implemented. On Friday we will hear from Members of Congress, the administration, and public policy organizations as to their views of title III.

With that, I would turn to Mr. Brown for any opening statement that he might have and any yielding he would care to do to members on his side for purposes of opening statements.

MR. BROWN. Thank you very much, Mr. Chairman, and I commend you for holding this hearing on title III of H.R. 9, and I also want to thank you for agreeing to my request for a second day or hearing on Friday.

Mr. Chairman, I have many concerns about H.R. 9, and I am even more concerned about the desire to meet the speaker's 100-day deadline, that that desire may deprive members of this committee an adequate opportunity to work together to perfect a bill that we can all support. We share with you the desire to pass risk assessment legislation that will help the Federal Government discharge its regulatory responsibilities.

We do have a few concerns about the bill. First, it may well be that the bill tries to tell scientists how to do science, requiring a mandatory "one size fits all" risk assessment process, and maybe

incorporating some dubious statistical assumptions. We all agree on the need to make the assumptions and limitation of risk assessments clear, but we also need to leave the science to scientists.

Second, H.R. 9 will add costs and delay to an already cumbersome regulatory process, will impose costly new information requirements on industry, and possibly require more bureaucrats and money for the agencies to implement it, legal loopholes might invite endless litigation, and we hope we can correct that.

Third, the broad scope of H.R. 9 sweeps in almost every Federal agency from nuclear plant licensing and child immunization programs to air traffic safety and work place safety laws. This committee has not had experience in many of these areas, and we will need to supplement our own historical background with considerably more information. I have asked each of the agencies involved in this bill to provide information, and I would like to submit for the record their responses as they are received.

Finally, while agency risk management decisions are often criticized for ignoring costs, the fact is that the Federal agencies are often just carrying out Congress' direction. For example, most of the Clean Air Act requires technology-based, not risk-based regulation. In the Endangered Species Act Congress said that the agencies could not consider costs in listing an endangered species. These and other kinds of problems cannot be corrected by the efforts of this bill but require changes in those laws.

Despite these concerns, Mr. Chairman, we share many of the same goals and we want to work with you and the administration to develop a sound bill.

I ask unanimous consent to revise and extend these brief remarks.

The CHAIRMAN. Without objection.

Mr. BROWN. And I would yield to Ms. McCarthy for any brief comments that she might have. You will, of course, note the time so that she doesn't exceed the five minutes.

The CHAIRMAN. Ms. McCarthy is recognized.

Ms. MCCARTHY. Thank you, Mr. Brown and Mr. Chairman, and I, too am very delighted to be a part of this effort undergoing title III of H.R. 9. I look forward to listening to the witnesses. I am anxious to work on reform of this particular measure. I bring to it my State experiences as a member of the Missouri General Assembly for 18 years.

I share Mr. Brown's concern about the fiscal impact, the indirect costs to State and local governments, so I am anxious for witnesses to speak to that, and also the costs to the taxpayers, the analysis and the peer review, and the other provisions that we will be considering in this measure. I need to know just what the impact will be for our taxpayers and for our State and local governments, but I do share the goal, Mr. Chairman, of visiting this issue and reforming this particular concern that we all share at the State and Federal and local level.

Thank you very much.

The CHAIRMAN. Thank you very much.

I will next go to our witnesses. If there are additional opening statements we would hope that they would be submitted for the record.

I am told that we have a couple of minutes on each side. Does the gentlelady from Maryland wish to be recognized briefly?

Mrs. MORELLA. Thank you very much, Mr. Chairman. I would like to, and I appreciate that.

I want to begin by commending you for your continuing leadership in bringing comprehensive risk assessment legislation before the Congress.

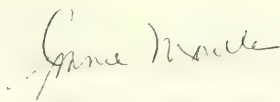
I don't think there is a single member here who would dispute the need for improved priority setting in governmental regulatory activities. We have had some very enlightening hearings on the subject of environmental regulation before the Science Committee during the last Congress. The joint EPA-Amoco Yorktown project, for example, suggested that we may be spending a great deal of money regulating some rather modest risks, meanwhile neglecting more significant risks that could be addressed more inexpensively. The startling conclusion of this first-of-a-kind study was that more than two-thirds of our expenditures on environmental compliance may be essentially wasted.

However, before we rush to discard the complete edifice of our environmental laws and regulations, we must recognize the very considerable benefits that these rules have provided to the American people. It wasn't very long ago, ladies and gentlemen, when our birds of prey faced imminent extinction from toxic pesticides like DDT, when acid rain from uncontrolled smokestack emissions threatened to sterilize the lakes and rivers of the northeast, when the Cuyahoga River in Ohio was so laden with chemical pollutants that it actually caught fire and burned.

Legislation to assist the regulatory agencies in prioritizing risks is in order. However, any new proposed law should satisfy a few basic criteria, and I am hoping that the witnesses will address some of the criteria I briefly mentioned. Does it significantly advance the protection of both the natural environment and the health of the American people? Is the law practical, affordable, and expedient to implement and enforce? Does the law provide adequate protection to sensitive populations such as children, pregnant women, the elderly, and people with chronic illness? Is adequate heed paid to health threats, other than just cancer, which has been the primary focus of risks assessments up to this point? Does the law effectively avoid the creation of cumbersome new bureaucracies and judicial remedies? And is there adequate provision for ongoing scientific research to improve and strengthen our risk assessment capabilities in the future?

I look forward to hearing the testimony, and again I thank you, Mr. Chairman.

[The prepared statement of Mrs. Morella follows:]



Hon. Connie Morella

Opening Statement for Risk Assessment Hearing  
January 31, 1995

Thank you, Mr. Chairman. I would like to begin by commending you for your continuing leadership in bringing comprehensive risk assessment legislation before the Congress. I don't think there's a single member here who would dispute the need for improved priority-setting in governmental regulatory activities.

We had some very enlightening hearings on the subject of environmental regulation before the Science Committee during the last Congress. The joint EPA-Amoco Yorktown project, for example, suggested that we may be spending a great deal of money regulating some rather modest risks, meanwhile neglecting more significant risks that could be addressed much more cheaply. The startling conclusion of this first-of-a-kind study was that more than two-thirds of our expenditures on environmental compliance may be essentially wasted.

However, before we rush to discard the complete edifice of our environmental laws and regulations, we must recognize the very considerable benefits that these rules have provided to the American people. It was not so long ago, ladies and gentlemen, when our birds of prey faced imminent extinction from toxic pesticides like DDT, when acid rain from uncontrolled smokestack

emissions threatened to sterilize the lakes and rivers of the Northeast, when the Cuyahoga River in Ohio was so laden with chemical pollutants that it actually caught fire and burned.

Legislation to assist the regulatory agencies in prioritizing risks is in order. However, any new proposed law should satisfy a few basic criteria:

- Does it significantly advance the protection of both the natural environment and the health of the American people?
- Is the law practical, affordable, and expedient to implement and enforce?
- Does the law provide adequate protection to sensitive populations, such as children, pregnant women, the elderly, and people with chronic illness?
- Is adequate heed paid to health threats other than just cancer, which has been the primary focus of risk assessments to date?
- Does the law effectively avoid the creation of cumbersome new bureaucracies and judicial remedies?
- Is there adequate provision for ongoing scientific research to improve and strengthen our risk assessment capabilities in the future?

I would ask the witnesses today to address themselves specifically to these various points, and I look forward to hearing their testimony. Thank you, Mr. Chairman.

The CHAIRMAN. I thank the gentlelady.

I think that pretty much utilizes the time on both sides so, as I say, we will be happy to take further opening statements for the record.

[The prepared statement of Mr. Roemer follows:]

Opening Statement, Rep. Tim Roemer, Committee on Science,  
Tuesday, January 31, 1995

Mr. Chairman, Risk Assessment is an important tool for our government regulators, one that should always be used, but used judiciously. I am pleased that we are here today to build on the efforts of Chairman Brown in the last Congress to clarify the risk assessment process and ensure its broad use.

Title III from the bill HR 9 seeks to establish a comprehensive and universal risk assessment for our federal government. This is a goal that I support, and I hope to vote for this measure.

However, due to the zeal that went into drafting this document, there may have been created a number of unintended consequences that we must explore today. Too often in the past we have enacted legislation intended to help business and industry that turned out to be a nightmare of bureaucratic red tape.

This legislation, while quite well-intended, has just such potential. Also, in creating the reform processes within this bill, quite a number of costs are created as well. We need to understand what these costs are, where they occur, and who will pay for them.

In examining this legislation today, and again during Friday's scheduled hearing, I hope the members of this committee will learn the answers to these questions so that we can mark up a vehicle that will enjoy broad bipartisan support in the House.

I want to commend Chairman Bob Walker for giving priority this important issue, and Ranking Member George Brown for already having established a foundation of knowledge on these matters in the 103rd Congress.

The CHAIRMAN. To each of our witnesses I would remind you that we would prefer you keep your opening statements very short. Without objection, all of your statements, as written, will be included in the record, but if we could hold your statements to five to seven minutes that would be very helpful to the committee.

As you can see, we have a number of members interested, and all of them are going to want to engage in some questioning of the panel, and so you would help us by keeping your statements reasonably short.

With that, we will go to our first witness, Jerry Jasinowski, the president of the National Association of Manufacturers, representing the Alliance for Reasonable Regulation.

Welcome, and we thank you for testifying this morning.

**STATEMENTS OF JERRY JASINOWSKI, PRESIDENT, NATIONAL ASSOCIATION OF MANUFACTURERS, REPRESENTING THE ALLIANCE FOR REASONABLE REGULATION; JOHN GRAHAM, PROFESSOR OF POLICY AND DECISION SCIENCES, HARVARD CENTER FOR RISK ANALYSIS; GORDON GARNER, EXECUTIVE DIRECTOR, LOUISVILLE AND JEFFERSON COUNTY METROPOLITAN SEWER DISTRICT; SAM KAZMAN, GENERAL COUNSEL, COMPETITIVE ENTERPRISE INSTITUTE; AND SCOTT HOLMAN, PRESIDENT/CEO, BAY CAST, INCORPORATED**

Mr. JASINOWSKI. Thank you very much, Mr. Chairman.

Thank you, the committee, for putting this high priority on an issue that I would suggest is the most important issue for American business, how to make the current regulatory system more cost effective and satisfactory to protecting our environment and safety.

I am president of the National Association of Manufacturers. I am testifying today on behalf of the Alliance for Reasonable Regulation. This coalition, Mr. Chairman, is almost nearly 1,000 companies and associations now, most of which are small companies of America and cover the full spectrum from the corner dry cleaner to the largest multinational companies. Collectively, we represent more than half of America's jobs and economic output, and I would say that this large coalition believes this is the number one priority for this Congress to do; that is, to make the current regulatory system more effective while protecting the environment and health of our citizens.

Our members have spent years complying with hundreds of Federal laws and thousands of Federal rules. We know what works on a company-by-company basis and what doesn't. In my own case, I formerly taught cost-benefit analysis, risk analysis, and cost effectiveness analysis at the Air Force Academy, and although my memory of all the technical aspects is rusty, I certainly am technically familiar with the material.

In our judgment, Mr. Chairman, it is time to change the system used to regulate threats to people and the environment. It is time for smart and sensible reforms to the regulatory system that apply sound science, good management, and wise economic judgment, risk-based reform of the kind found in title III of H.R. 9.

Let me say that the basic thrust of my views is that we can do the system smarter and better, and it is based on the hundreds of

examples in the private sector where we have applied Total Quality Management and restructured our companies and found ways to improve quality while reducing cost. I reject the notion that these proposals are going to cost a lot more money or require a much more extensive bureaucracy; I don't think that is the case.

In our companies, on average in the last decade, manufacturing companies, we have reduced the costs of our operation by on average 20 percent and we have at the same time become very much more successful in terms of quality today, and I have just returned from the World Economic Forum in Davos, Switzerland, where the American economy was regarded as number one in terms of its overall competitiveness. Now that change in the private sector I suggest is a major lesson for how we can restructure our environmental health and other bureaucracies and do more with less in general, and we must do more with less, ladies and gentlemen, because this is a time of scarce resources. We do not have the luxury of being able to do everything we want to do, and, beyond that, today we spend, private businesses, about \$140 billion a year on rules designed to protect the environment. That is on par with medicaid. Spending on all Government regulations, according to one academic estimate, amounts to \$60 billion a year. That is equal to Social Security and defense spending combined.

Since most regulatory costs fall on local governments and the private sector, they are off budget and out of sight to lawmakers. Government regulations amount to a giant hidden tax on American families of roughly \$6,000 a year. Mr. Chairman, these hidden costs have a terrible toll on the economy. Complying with these rules in many cases reduces our productivity, decreases innovation, and causes fewer jobs. When engineers spend their time filling out unnecessary Government forms instead of improving production methods, productivity suffers.

A clean environment is in everyone's best interests, but it is worth noting that there is a Census Bureau study, as indicated in my longer statement, that calculates for every dollar spent controlling pollution, businesses lose three to four dollars in productivity. We must spend smarter. We must dramatically change the system. We must do the kind of things that the private sector has done with respect to its own restructuring and improved efficiency, and we have the capability from both the scientific and comparative point of view to do that.

This is important, Mr. Chairman, because productivity is the name of the game in today's global economy. Success is defined by who is smarter in the use of people, technology and capital. High priced Government regulations, however well intentioned, handicap business in this global economy and our generation of growth in jobs.

I have, Mr. Chairman, in my longer statement many specific examples: A Superfund site in New England where the Government ordered a \$9.3 million cleanup to make the dirt at the site clean enough to eat five times a week. The site sits in the middle of a swamp. I can give you plenty of examples where we are now doing things that are not effective, they don't make sense, in some cases they are down right silly.

Our desire is not to try to roll back and eliminate coverage, our argument is that we can have the current level of coverage, in some cases we can improve the coverage, for environmental health and safety, and we can do it in a more cost-effective manner.

I have a rather long statement, Mr. Chairman, that I have—I would like included, which goes into the details of our comments on all aspects of section 3. We are very supportive of the direction in which that heads. We have a lot of suggestions with respect to how to strengthen it, in some cases how to make it more flexible, and I would be prepared to respond to all those questions, Mr. Chairman, as we move forward.

Thank you for letting me testify today.

[The prepared statement of Mr. Jasinowski follows:]



ALLIANCE FOR REASONABLE REGULATION

**Statement of Jerry J. Jasinowski  
on Behalf of the  
Alliance for Reasonable Regulation  
Regarding Title III of H.R.9  
Risk Assessment and Cost/Benefit Analysis for New Regulations**

**Introduction**

My name is Jerry J. Jasinowski. I am the President of the National Association of Manufacturers (NAM), and I am submitting this Statement on behalf of the Alliance for Reasonable Regulation (ARR), an organization of which NAM is a founding member. This Statement presents the views of ARR on Title III of H.R.9, which establishes requirements for risk assessment and communication, cost-benefit analysis, and peer review of designated categories of agency rules. As discussed below, ARR strongly supports the concepts reflected in this important legislation, which we believe will allow our society to enjoy both a healthy environment and a strong competitive economy.

ARR is a broad-based coalition of nearly a thousand trade associations and individual companies, large and small, from all across the United States. (A list of ARR members is attached to this Statement.) ARR members place a high priority on the health and safety of their employees, their customers, the general public, and the environment in which we live. At the same time, they have come to the conclusion that current federal regulatory policy lacks proper direction and does not achieve

society's health, safety, and environmental objectives in an efficient and cost-effective manner.

Although they are engaged in a great variety of different enterprises, ARR members have joined together to support a common goal: namely, the enactment of legislation that will require the use of sound science, sound risk assessment, and sound economics in regulatory decisionmaking. Members of the Alliance are pursuing this goal because they believe that the environment and the health and safety of the American people can be protected most effectively and efficiently by:

- Policies and decisions that are designed to protect the public and the environment by considering all relevant risks and establishing risk-reduction priorities that allow the available resources to be used most efficiently and cost-effectively.
- Health, safety, and environmental laws and regulations that are based on the best available science.
- Scientifically sound, adequately characterized, and peer reviewed risk assessments that are conducted for significant regulatory actions designed to protect human health and the environment.
- Comparison of the risks addressed by regulatory actions with other risks to which people are routinely exposed.
- A process that guarantees the public access to all information used to develop regulatory actions and policies and encourages participation in evaluating risks and making risk management decisions.

- Consideration of both societal costs and projected benefits of health, safety, and environmental regulation.
- Rules structured with a performance-based orientation that maximizes the cost-effectiveness of agency interventions.
- A requirement that the foregoing principles regarding --
  - + use of the best available science,
  - + conduct of sound, peer reviewed risk assessments, and
  - + development of cost-effective rules whose benefits justify their costs
 be applied to regulatory actions taken under all statutes relating to the protection of health, safety, or the environment.
- A mechanism that would allow existing rules and regulations to be reexamined and, where appropriate, revised to reflect the foregoing principles.

By enacting into law a regulatory process that reflects the foregoing points, Congress would establish a framework for the promulgation of "smarter" regulations by a leaner, more effective government -- thereby showing itself to be responsive to the message delivered by the voters last November and to a central theme of the President's State of the Union Address. At the same time, Congress would demonstrate that it is possible to reconcile what are sometimes viewed as the competing demands of productive, job-creating growth and responsible environmental stewardship.

Recently, Paul Portney, Vice President of Resources for the Future, observed that "much good can come from a careful rethinking of the way we assess risks to health and the environment and the role we accord to economic costs in setting regulatory goals."<sup>1/</sup> Title III of H.R.9 provides a mechanism for achieving precisely that kind of "rethinking." For that reason, while we do have reservations about particular provisions of the bill and believe there are important additional points that should be covered, we are pleased to offer our strong support to the basic concepts embodied in the legislation.

In the balance of this Statement, I want to discuss more fully some of the shortcomings of our current approach to health, safety, and environmental regulation and to explain what ARR believes needs to be done to remedy these deficiencies. The Statement concludes with a specific evaluation of Title III of H.R.9.

I. Why Is Risk Legislation Like Title III of H.R.9 Needed?

The short answer to the question of why we need to enact legislation like H.R.9 is that we live in a world of limited resources and competing needs. We are beset by a host of social problems and economic challenges, each of which places compelling demands on our resources. Yet we have no system for

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<sup>1/</sup> The Washington Post, January 15, 1995, p. C3.

making rational, well informed, carefully considered decisions as to how those limited resources should be allocated in order to maximize the net benefits to society. For example, hazardous waste sites rank relatively low on the Environmental Protection Agency's list of environmental risk priorities.<sup>2/</sup> Yet in 1993, the Federal government alone spent more than twice as much on hazardous waste cleanups as on cancer, heart disease, and AIDS research combined. Whether this allocation of Federal resources makes sense is certainly an open question. But it illustrates the fact that choices must be made, and right now they are being made without a clear understanding of what we are buying for what we are spending.

At the same time, we find ourselves in the midst of what has been termed the "second industrial revolution," in which competition has assumed a global dimension. If we fail to maintain and improve our productivity, we will be unable to compete successfully in the global marketplace, create jobs for our workforce, keep real wage levels from falling, and address the many difficult and demanding problems that confront us in other areas.

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<sup>2/</sup> See Reducing Risk: Setting Priorities and Strategies for Environmental Protection (September 1990) (hazardous waste sites not identified as a high priority risk either to human health or to natural ecology and human welfare).

The importance of ensuring that we regulate wisely and efficiently is related directly to the enormous costs that Federal regulations impose on our economy and society. Professor Thomas D. Hopkins of the Rochester Institute of Technology estimates that the "hidden" costs of Federal regulation in 1993 totaled \$581 billion (in 1991 dollars), or more than \$5,900 per family.<sup>3/</sup> Although these costs are not always directly visible (since they are initially borne by businesses and Federal, state, and local governments), they are passed on to Americans in a variety of ways -- such as lower wages for employees, higher prices for consumers, increased state and local tax burdens, slower economic growth and job creation, and reduced employment opportunities.

The fastest growing regulatory costs have been in the area of environmental and health and safety protection. According to the General Accounting Office, as of 1990, U.S. industry and government were spending about \$115 billion per year, equivalent to about 2.1 percent of our total Gross National Product (GNP), to control pollution and achieve environmental goals.<sup>4/</sup> And those expenditures have been increasing substantially each year. Thus, the cost of complying with EPA

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<sup>3/</sup> T.D. Hopkins, "The Costs of Federal Regulation," revised version of a paper that appeared in the Journal of Regulation and Social Costs in March 1992.

<sup>4/</sup> See GAO Report to Congress, "Meeting Public Expectations with Limited Resources," p. 8 (June 1991).

regulations had reached \$140 billion (equal to 2.2 percent of Gross Domestic Product) in 1994,<sup>5/</sup> and it is expected to reach \$160 billion by the end of the decade.<sup>6/</sup> EPA itself estimates that environmental spending will equal 2.8 percent of GNP by the year 2000, and that estimate assumes that only \$9.5 billion will be spent on hazardous waste site cleanup activities in the year 2000.<sup>7/</sup> Other estimates, such as a study conducted by the University of Tennessee, are far higher.

Whatever the exact figure ultimately turns out to be, there is no question that these are large sums by any measure. And, contrary to the arguments heard in some quarters, these expenditures, for the most part, are not recovered in the form of increased efficiency, even when they are spent on direct pollution abatement measures rather than on cleanup efforts. According to the Bureau of the Census, only 9.2 percent of pollution abatement costs in the chemical industry were recovered in the form of increased efficiency in 1991, a finding that is consistent with subsequent chemical industry surveys. Similarly, a recent Bureau of the Census study found that productivity in

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<sup>5/</sup> See Paul Portney, "Chain-Saw Surgery: The Killer Clauses Inside the 'Contract,'" The Washington Post, January 15, 1995, p. C3.

<sup>6/</sup> See id.; GAO Transition Series, "Environmental Protection Issues," (December 1992).

<sup>7/</sup> U.S. EPA, Environmental Investments: The Costs of a Clean Environment (December 1990).

three major industry sectors (oil refineries, paper mills, and steel mills) was reduced by the equivalent of 3 to 4 dollars for each dollar of pollution abatement costs incurred during the period 1979 through 1985.<sup>8/</sup> And a privately funded study estimated that GDP was reduced by 2.6 percent relative to trend in the period 1972-1985 as a result of environmental regulation.<sup>2/</sup>

Obviously, when environmental regulatory expenditures are this large, they must be made wisely, for, as Senator Baucus testified before the Senate Energy and Natural Resources Committee in November 1993: "We do not have unlimited resources."<sup>10/</sup> Indeed, as John D. Graham, Director of the Harvard Center for Risk Analysis notes:

"[T]he reality of scarcity is more apparent today than ever before. . . . [T]he scarce human and material resources devoted to environmental protection are resources that we cannot use to combat crime, educate our children, reduce poverty, improve health care, strengthen our national defense, and

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<sup>8/</sup> See "Measuring the Productivity Impact of Pollution Abatement," Bureau of the Census Statistical Brief SB/93-13 (November 1993).

<sup>2/</sup> D. Jorgenson & P. Wilcoxon, "Impact of Environmental Legislation on U.S. Economic Growth, Investment and Capital Costs," in American Council for Capital Formation, U.S. Environmental Policy and Economic Growth, ACCF Monograph Series (Washington, D.C. 1992).

<sup>10/</sup> Testimony of Senator Max Baucus to the Senate Energy and Natural Resources Committee, November 9, 1993 (hereinafter "Baucus Testimony") at 2.

meet the basic needs of citizens and their families."<sup>11/</sup>

Clearly, with so "many problems to solve and [so] many difficult choices to make," our environmental policy "must move in a direction that will give us the greatest return on our investment."<sup>12/</sup> As a blue ribbon panel of the Carnegie Commission points out: "The economic burden of regulation is so great, and the time and money available to address the many genuine environmental and health threats so limited, that hard resource allocation choices are imperative."<sup>13/</sup> Unfortunately, we have not been very successful in allocating our health, safety, and environmental protection resources most effectively. Instead, as a careful student of the subject, Supreme Court Justice Stephen Breyer, has concluded: "Our regulatory system badly prioritizes the health and environmental risks we face."<sup>14/</sup>

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<sup>11/</sup> Testimony of John D. Graham, Ph.D. before the Senate Committee on Energy and Natural Resources, November 9, 1993, at 2.

<sup>12/</sup> See Baucus Testimony at 2; GAO Report to Congress, "Meeting Public Expectations with Limited Resources," June 1991, at 8 (our environmental expenditures must be made in a way that "yield[s] maximum returns on [the] investment").

<sup>13/</sup> Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making (June 1993) (hereinafter "Carnegie Commission Report") at 118.

<sup>14/</sup> Testimony of Stephen Breyer before the Senate Committee on Energy and Natural Resources, November 9, 1993, at 2.

Justice Breyer's view is widely shared. Many close observers of the process have emphasized that during the last two decades, "environmental policy has too often evolved largely in reaction to popular panics, not in response to sound scientific analyses of which environmental hazards present the greatest risks."<sup>15/</sup> The result, as EPA's Science Advisory Board noted in a widely quoted study, is that regulatory attention often has been focused on less significant environmental risks while, overall, our environmental protection efforts "have been . . . less effective than they could have been."<sup>16/</sup> By setting priorities on a "chemical of the month" basis, the Carnegie Commission panel points out, we wind up overregulating some hazards, underregulating others, and reducing agency credibility.<sup>17/</sup> This clearly is not a sensible way to proceed. Federal agencies must establish sensible risk-based priorities for their regulatory interventions, so that substantial resources are not devoted to achieving trivial reductions in risk while much more significant public health or environmental problems are slighted.

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<sup>15/</sup> Keith Schneider, "New View Calls Environmental Policy Misguided," New York Times, March 21, 1993.

<sup>16/</sup> See Reducing Risk: Setting Priorities and Strategies for Environmental Protection (September 1990).

<sup>17/</sup> See Carnegie Commission Report at 73.

The shortcomings of our present regulatory system are not limited to the absence of a rational method for setting regulatory priorities. Major problems also are evident in the way in which health, safety, and environmental regulations are developed, structured, and implemented. These include the following:

- Risk assessments, when they are conducted at all, tend to be unrealistic, overly conservative, and reflective of unstated policy choices or default assumptions which, if they must be included in the risk assessment at all, should be explicitly acknowledged and fully explained.

- In most cases, health and environmental risks are inadequately characterized and communicated to decisionmakers and interested members of the public.

- In most cases, the scientific and technical assessments on which regulations are based are not subjected to independent external peer review. As a result, the scientific and technical underpinnings of agency actions that may have enormous consequences often are not adequately tested.

- Environmental regulations sometimes are set at a level of stringency that imposes exceedingly large

costs but achieves little, if any, incremental environmental or public health benefit.

- The economic and other adverse impacts of agency rules (including the creation of what H.R.9 refers to as "substitution risks") frequently are not evaluated adequately or are not factored into the ultimate regulatory decision.

- Agency rules tend to be relatively inflexible, reflecting a penchant for command-and-control specification, rather than a performance-based orientation. This results in regulations that are far less cost-effective than they could be, and it frequently precludes the adoption of environmental management practices that would actually be more protective and less costly than the actions required under the rule.

- Alternatives to proposed regulatory actions (whether they be non-regulatory, voluntary, market-based or regulatory in nature) frequently do not receive the attention they deserve.

- The process by which agencies conduct hazard evaluations and risk assessments is not as open to public participation as it should be.

This flawed process for developing health and environmental protection rules, combined with substantive standards or requirements that may force agencies to make ill-advised decisions, too often results in what The Washington Post recently described as regulations that "have gone way too far or are monuments to illogic."<sup>18/</sup> Examples of such nonsensical or counterproductive regulatory actions are legion. The Superfund program, in particular, is fertile ground for these regulatory "horror stories." Justice Breyer, for example, points to a case that was before the U.S. Court of Appeals for the First Circuit for ten years when he was the Chief Judge of that Court. In that case, the government was demanding an additional \$9.3 million cleanup after everyone conceded that, on the basis of the original cleanup, a person could safely eat dirt at the site 70 days a year. The government wanted dirt that would be safe to eat 245 days per year -- even though the site was a swamp.<sup>19/</sup> This is the kind of action that led former New Jersey Governor and Superfund author Jim Florio to exclaim: "It doesn't make any sense to clean up a rail yard in downtown Newark so it can be a drinking water reservoir."

Another example involves estimates of health risks at hazardous waste sites in Butte, Montana, and Midvale, Utah.

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<sup>18/</sup> The Washington Post, January 23, 1995, p. A18.

<sup>19/</sup> See S. Breyer, Breaking the Vicious Circle: Toward Effective Risk Regulation (1993), pp. 12-13.

Using a conservative mathematical model, EPA calculated the blood lead levels that it predicted would be found in children in the two communities after the required cleanup was completed. In fact, however, the predicted post-cleanup blood lead levels were twice as high as the levels actually measured in the children before the cleanup was undertaken.<sup>20/</sup>

A somewhat different point is illustrated by the ambitious joint pollution prevention study conducted by EPA and the Amoco Corporation at Amoco's Yorktown, Virginia refinery several years ago. A key finding of the study was that if the company had been free to pursue a flexible, performance-oriented approach, 90 percent of the emissions reductions required under applicable regulations could have been achieved for 20-25 percent of the cost of meeting the specific requirements of the regulations.<sup>21/</sup> Union Carbide Corporation has had a similar experience at its Taft, Louisiana plant, where a requirement to meet inflexible effluent discharge limitations forced the company to employ "end-of-pipe" technology, rather than implementing alternative source reduction projects that would have achieved a

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<sup>20/</sup> See Paul Portney, "Chain-Saw Surgery: The Killer Clauses Inside the 'Contract,'" The Washington Post, January 15, 1995, p. C3.

<sup>21/</sup> Under a performance-oriented approach, releases at the refinery could have been reduced at an average cost of \$510 per ton, as opposed to the \$2,400 per ton average cost of achieving reductions under EPA's prescriptive command-and-control regulations.

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greater overall reduction in waste generation and pollutant releases to all media, while enabling the company to recover valuable product.

The lesson in all this is clear: We cannot afford poorly targeted, inefficient regulations that achieve only marginal environmental and risk reduction benefits in an inflexible manner and at an excessive cost. We must spend our limited resources wisely -- learning to do more with less and making "smart" regulatory decisions that produce more "bang for the buck" in terms of overall health, safety, and environmental protection.

## II. What Needs To Be Done?

In order to remedy the existing process for identifying and regulating health, safety, and environmental risks, a number of steps must be taken:

1. Federal agencies must develop a more rational, risk-based system to evaluate (and set priorities for the regulation of) risks to human health, safety, and the environment. We envision this system as having two broad components:

- (a) A government-wide comparative risk analysis that can be used as general guidance for both Congress

and the Executive Branch to allocate resources across agencies and programs dealing with the protection of human health, safety and the environment.

(b) Within each agency, an evaluation and ranking of the various health, safety and environmental risks falling within the agency's jurisdiction. Based on that evaluation and ranking, each agency should shape its regulatory agenda, strategic plan, budget requests, enforcement activities, and research programs so as to give priority to those areas where the greatest overall reduction in the most serious risks can be achieved in a cost-effective manner.

2. Agencies must improve their risk assessment methodologies and the accuracy and relevance of the resulting risk estimates and characterizations. This implies several things:

(a) Risk assessments must be based upon all reasonably available scientific information, including data that may indicate the absence of risk.

(b) The results of a risk assessment should emphasize the most plausible and realistic estimates of risk that can feasibly be developed for the relevant exposed populations or ecological species. These

estimates of risk should be placed in perspective by comparison both to other risks within the agency's jurisdiction and to risks more commonly understood by the public.

(c) Risk assessments should distinguish clearly between scientific findings and policy decisions.

(d) As a corollary of this last point, risk characterizations should describe the results of the risk assessment fully and objectively, identifying clearly all of the default inferences, uncertainties, assumptions, and limitations contained in the risk assessment.

(e) The conduct of risk assessments should be tiered, so that the depth and rigor of analysis are commensurate with the potential consequences of the decision(s) that may be based on the risk assessment.

(f) Risk assessment and risk characterization requirements need not apply to internal screening assessments that are not used to support agency regulatory actions.

(g) Federal agencies should perform independent risk assessments in connection with regulatory actions they plan to implement. An agency should not rely

solely on risk assessments or hazard evaluations performed by some other entity, without exercising its own independent judgment and providing an opportunity for public comment. This is particularly true where the outside entity did not observe the principles set forth in Title III of H.R.9 or allow for open public participation in developing its risk assessment or hazard evaluation.

3. In order to ensure that risk-based decisions have a sound scientific and technical underpinning, any risk assessment that may potentially serve as the basis for a major rule should be subjected to independent, external peer review. As in the case of risk assessments themselves, the peer review process should be tiered -- with more extensive peer review being given to issues that are of greater significance and complexity.

4. Opportunities for public participation in the hazard evaluation and risk assessment process should be increased -- both prospectively and, in appropriate cases, retrospectively as well. What we have in mind by this latter point is the establishment of a process for petitioning an agency to review (or to secure peer review of) particular risk assessments or health and environmental risk values that the agency conducted or developed in the past on the basis of information or methodologies that have since been found to be inadequate.

5. The risk management decisionmaking process must be improved in a number of respects.

(a) Rules relating to the management of health, safety, or environmental risks should be flexible, cost-effective, and, to the maximum extent possible, performance-based. Standards should be expressed in terms of objective criteria or descriptions of the performance desired, and regulated entities should be given flexibility to decide how to meet those criteria or to achieve those performance-based results.

(b) Agencies should be compelled to evaluate the costs and benefits of major rules, so that they can ensure, to the extent practicable, that the rules they adopt are likely to produce significant reductions in risk and other benefits that will justify the costs and other adverse effects of implementing and complying with the rule. In this connection, among the adverse effects agencies should be required to consider are the risks associated with the use of alternative substances or courses of action that are likely to be substituted for substances or activities regulated under the rule.

(c) The requirements outlined in paragraphs (a) and (b) above should apply to actions taken under all statutes addressing risks to health, safety, or the

environment, notwithstanding any contrary provisions of the particular enabling statute pursuant to which the agency is acting.

(d) In connection with the development of all major rules addressing risks to health, safety, or the environment, agencies should be required to consider a range of reasonable alternatives (including potential nonregulatory alternatives) and to select as its final action the alternative that is believed to be the most cost-effective and flexible approach to achieving the regulatory objective.

6. There should be a mechanism under which existing rules and regulations can be reexamined and, where appropriate, revised to reflect the foregoing principles.

### III. Specific Comments on Title III of H.R.9

In this section of the Statement, I want to turn my attention to the specific provisions of Title III. I will address both what the legislation does provide and, of equal or greater importance, what it fails to provide. Let me begin with the latter.

**Risk-Based Prioritization**

As discussed in Parts I and II of this Statement, ARR believes there is a crying need to put in place a system under which Federal agencies would be required to evaluate the risks to human health, safety and the environment falling within their respective jurisdictions and set priorities to address those areas where the greatest overall reduction in the most serious risks can be achieved in a cost-effective manner. These risk-based priorities should shape the agency's regulatory agenda, funding requests, research programs, and enforcement activities. At the same time, a government-wide comparative analysis of risks should be undertaken in order to provide guidance for the allocation of risk-reduction resources across agencies and programs.

Title III of H.R.9 does require agencies to apply designated principles for risk assessment and risk characterization/communication. It does not, however, provide for a system of setting risk-based priorities to help guide the allocation of public and private resources in ways that will allow us to achieve the most substantial risk reduction benefits overall with our limited resources. We view this as a major failing of what, in most respects, is a well-conceived approach to risk assessment and risk characterization. Legislation already introduced in the House by Congressman Zimmer (H.R.690)

and in the Senate by Senator Moynihan (S.123) addresses the important issues of risk-based prioritization and comparative risk analysis. Title III of H.R.9 should address these important issues as well.

#### Risk Management Issues

Subtitle B of Title III establishes cost-benefit analysis requirements for major rules designed to protect human health, safety or the environment. We are pleased that these provisions are included in the bill, and we will have more to say about them shortly. We are concerned, however, that Title III does not direct Federal agencies to structure their rules with a view to giving regulated entities maximum flexibility to comply with performance-based standards in the most cost-effective manner. We believe this important regulatory principle should be added to Title III.

At the same time, while we are pleased that Title III requires assessments of the incremental costs and risk reduction benefits of major rules, we are concerned about the absence of standardized methodologies for assessing regulatory costs. We believe the Office of Management and Budget should be directed to develop and issue cost estimation guidelines that Federal agencies would be required to follow in assessing the costs of their regulatory actions. These guidelines should be subject to

public comment, and they should reflect any recommendations emanating from a study, to be conducted by the President, which compares the actual costs of randomly selected regulations to the estimated costs of those regulations.

A final point that should be made clear with regard to risk management issues is the relationship of Title III's cost-benefit assessment requirements to existing enabling statutes. We believe all major rules addressing risks to health, safety, or the environment should be supported by a cost-benefit justification, wherever practicable. This is an important way of ensuring that our regulatory interventions are indeed "smart," as the President correctly says they should be. Unfortunately, Title III of H.R.9 does not make clear whether and how the cost-benefit justification requirement of Subtitle B applies when an agency is acting under an enabling statute that does not appear to allow cost-benefit considerations to be a determining decisional factor. As a result, provisions such as the Delaney Clause of the Federal Food, Drug, and Cosmetic Act (which allows a product to be banned even though it presents no significant risk) or Section 112 of Clean Air Act (which allows costly regulation of a process that presents no significant risk) could continue to produce unjustified regulatory outcomes even if Title III is enacted into law.

In order to avoid any ambiguity on this point, Title III should state explicitly that the benefit-cost justification requirement of Subtitle B applies to all major rules covered by that Subtitle, notwithstanding any contrary provision of the enabling statute pursuant to which the agency is acting. In addition, as noted in Part II above, we believe there should be a mechanism (e.g., a petition process) that would allow existing rules and regulations to be targeted for reexamination and, where appropriate, revision, to reflect cost-benefit considerations and the other risk management principles discussed above.

#### Public Participation

Title III requires that an opportunity for public comment be provided in connection with the President's issuance of guidelines for risk assessment and risk characterization. It does not, however, provide an opportunity for public comment in connection with the preparation of a risk assessment by an agency. While many agency risk assessments may be subject to public comment if they are used directly to support the promulgation of a legislative-type rule, other risk assessments may be made publicly available and used by an agency outside the context of a rulemaking proceeding. Although such risk assessments may have a significant impact on persons outside the Federal government, there may be no opportunity for public input into the risk assessment. There is a need to provide an

opportunity for public participation in the development of any risk assessment that may have a significant impact on persons outside the Federal government, even if the risk assessment is not immediately being used to support a legislative-type rule.

**Subtitle A: Risk Assessment/Risk Characterization**

By and large, AAR is very supportive of the risk assessment and risk characterization provisions contained in Subtitle A of Title III. There are, however, a number of respects in which we believe the provisions of Subtitle A can be improved, supplemented, or clarified.

For one thing, Subtitle A should explicitly recognize that the depth and rigor of a risk assessment should be commensurate with the potential consequences of the decision(s) that may be based on the risk assessment. Section 3301(a)(2) explicitly recognizes this point with respect to the peer review requirements of Subtitle C. A similar "tiering" provision should be included in Subtitle A with regard to risk assessment requirements.

A related point involves the requirement that risk characterizations present the "best estimate" of risks to specific populations. While we believe that best estimates should be provided when quantitative evaluations of risks are made, we believe that qualitative assessments of hazard also

should reflect the agency's best "estimate" of whether exposure to a potential toxin or environmental stressor actually does, or is likely to, present a hazard. Subtitle A should make clear that the "best estimate" requirement applies to qualitative as well as quantitative assessments.

In addition to the foregoing, there are a number of minor modifications or clarifications that should be made in the provisions of Subtitle A, including the following:

- The "savings provisions" in Section 3103(c) should be revised to make clear that the risk assessment and risk characterization requirements of Subtitle A apply to all risk assessments covered by the Subtitle, regardless of the enabling statute under which the agency is acting. The fact that Subtitle A does not modify any statutory standard or requirement should not be interpreted to mean that the risk assessment and risk characterization principles established pursuant to Subtitle A need not be applied under particular enabling statutes.

- In Section 3103(b)(2)(A)(ii), the words "registration or" should be inserted after the word "product" on page 36, line 21, to recognize that screening analyses may be prepared in connection with product registrations, as well as reregistrations.

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- The principles for risk assessment in Section 3104 properly require agencies to identify and explain the plausible and alternative assumptions, inferences, or models considered in preparing a risk assessment. However, we believe that Section 3104 also should require agencies to use actual data, instead of default assumptions, whenever such data are reasonably available.

- Section 3105 sets forth principles for risk characterization and communication that are to be applied when agencies characterize risk in any risk assessment document, regulatory proposal or decision, report to Congress, or other document which is made available to the public. Section 3105 also should require that a clearly understandable summary of the risk characterization be included in the Federal Register notice for any proposed or final rule for which the risk assessment was prepared.

- Section 3106(a) requires the President to issue risk assessment and characterization guidelines that address specific subjects. We believe this approach is overly prescriptive. In our view, it would be preferable for Congress to set more general requirements regarding the types of information and

issues to be addressed in the guidelines -- such as discussions of alternative risk assessment methodologies and assumptions and the rationale for choosing among them.

• Section 3106(b) requires each Federal agency to publish and implement a plan to review and revise any risk assessment published before completion of the plan, if the agency determines that new information or methodologies are available that could significantly alter the results of the risk assessment. We are concerned that a wholesale review and revision of past risk assessments may not be the best use of agency resources. It may be preferable to provide a more targeted approach to reviewing past risk assessments. One possibility would be to establish a mechanism under which interested parties can petition agencies to review particular risk assessments, with an obligation on the part of the agency to respond within a specified period of time.

Subtitle B: Analysis of Risk Reduction Benefits and Costs

Apart from the points addressed above under the heading "Risk Management Issues," our suggestions regarding the cost-benefit analysis requirements of Subtitle B are as follows:

- Section 3201(a) directs the President to require Executive Branch agencies to prepare a cost-benefit analysis for each major rule designed to protect human health, safety, or the environment. We do not understand why Congress does not simply place this requirement upon the agencies directly. Interposing the President as a middleman in the process is unnecessary and could create an impediment to accomplishing the objectives of Subtitle B. If the President, for whatever reason, chose not to require Executive Branch agencies to prepare cost-benefit analyses, the agencies themselves could elect not to do so without violating Section 3201. There is no reason to structure Subtitle B in a way that could allow such an outcome. Accordingly, the words "the President shall require" should be deleted from Section 3201(a), and the word "shall" should be substituted for the word "to" on page 45, line 22.

- Although it may implicitly be included in Section 3201(a)(2), Subtitle B does not explicitly require agencies to include a description and estimate of the risk being addressed by each major rule in the analysis of risk reduction benefits and costs that is prepared for the proposed and final rule. Such a requirement should be made explicit.

- Consideration may have to be given to providing a definition of the term "benefits" as used in Subtitle B. The definition of the term "costs" also may have to be expanded to indicate that it includes adverse effects in addition to those that are directly economic in nature.

- Unless we misunderstand it, Section 3201(a)(4) merely duplicates an assessment that already is required under Section 3201(a)(1). If we are correct, Section 3201(a)(4) should be deleted.

#### Subtitle C: Peer Review

Our suggestions regarding the peer review provisions of Subtitle C are as follows:

- The "major rules" to which the peer review requirements of Subtitle C apply are defined differently from the "major rules" to which the cost-benefit analysis requirements of Subtitle B apply. We believe the definition of "major rule" should be the same for both purposes. One possibility would be to use a basic \$50 million threshold in both cases.

- We believe the peer review requirements may be somewhat misdirected. Rather than requiring review of

the scientific and economic information per se, peer review should be required for the analyses or assessments that are prepared on the basis of such information.

- Section 3301(c) appears to be overly prescriptive as regards the content of a peer review report. The nature of a peer review will depend on the nature of the document being reviewed. We do not believe it is necessary or wise for Congress to specify what must be addressed by the peer reviewers or the precise form that their report must take.

- Subtitle C should include a provision assuring protection for any trade secrets or other confidential business information that is provided to peer reviewers. For example, agencies might be directed to enter into confidentiality agreements with peer reviewers in appropriate cases.

### Conclusion

In closing, I want to reiterate ARR's strong support for the important concepts reflected in Title III of H.R.9. We believe that, with the modifications and clarifications we have suggested, the bill will establish a framework for achieving impressive risk reduction benefits in a cost-effective manner and

will provide Americans assurance that the vast resources being devoted to protection of human health, safety, and the environment are being spent wisely and well.



ALLIANCE FOR REASONABLE REGULATION

**ALLIANCE FOR REASONABLE REGULATION****LIST OF MEMBER COMPANIES & ASSOCIATIONS**

(As of January 30, 1995)

A-1 Plating Company, Inc.  
 A F K Corporation  
 A. O. Smith Corporation  
 A.I.O. Auto Brokers Inc.  
 Abbott Laboratories  
 Abrasive Diamond Tool Company  
 ABS Corporation  
 Ace Metal Fabricators, Inc.  
 Acme Auto Headlining Company  
 Acme Battery Manufacturing Company  
 Acme Manufacturing Company, Inc.  
 Acraline Products  
 Acro Extrusion Corporation  
 Ada Beef, Inc.  
 Adams Truss Inc.  
 Adapting Technologies, Inc.  
 Advance Bronze Inc.  
 Advanced Cast Products, Inc.  
 Advanced Fiber Products  
 Aero Metal Finishing, Inc.  
 Aetna Machine Company  
 Ag Processing, Inc.  
 AGA Gas Incorporated  
 Agri-Cel, Inc.  
 Agricultural Retailers Association  
 Air-Conditioning & Refrigeration Institute  
 ALANCO Manufacturing Company  
 Albemarle Corporation  
 Alcotec Wire Company  
 Aldan Rubber Company  
 Alfab, Inc.  
 All Steel Fabricating Company, Inc.  
 Alliance of American Insurers  
 Allied Automation, Inc.

Allied Moulded Products, Inc.  
 Allstate Medical Products, Inc.  
 Alpha Heat Treaters  
 Alsey Refractories Company  
 Alta Photographic, Inc.  
 Aluminum Hard Coat Company  
 Amadas Industries  
 American Architectural Manufacturers Association  
 American Automotive Leasing Association  
 American Bakers Association  
 American Boiler Manufacturers Association  
 American Cap Company, Inc.  
 American Chrome & Chemicals, Inc.  
 American Conservative Media Network  
 American Consulting Engineers Council  
 American Electric Power Service  
 American Feed Industry Association  
 American Fiber Manufacturers Association  
 American Forest & Paper Association  
 American Foundrymen's Society  
 American Fuji Seal, Inc.  
 American Furniture Manufacturers Association  
 American Greetings Corporation  
 American Home Products Corporation  
 American Industrial Health Council  
 American Industrial Hygiene Association  
 American Institute of Chemical Engineers  
 American Institute of Merchant Shipping  
 American International Group Inc.  
 American Iron & Supply Company  
 American Iron and Steel Institute  
 American Lawn Mower Company  
 American Linc Corporation  
 American Microtrace Corporation  
 American Mining Congress  
 American National Can Company  
 American Petroleum Institute  
 American Plastics Council  
 American Road & Transportation Builders Association  
 American Rockwool, Inc.  
 American Sports International  
 American Steel Container Company  
 American Tinning & Galvanizing Company  
 American Trucking Association

American Wire Producers Association  
 American Wood-Preservers Association  
 American Zinc Association  
 Amko Plastics Inc.  
 Amway Corporation  
 Anchor Fabricators Inc.  
 ANEZ Industries, Inc.  
 Apollo EDM Company  
 APPA: The Association of Higher Education Facility  
 Appleton Lumber Company Inc.  
 Aptus, Inc.  
 Aqua Clear Industries, Inc.  
 ARCO  
 Aristocrat Stamping & Manufacturing Company  
 Arkansas Face Veneer Company, Inc.  
 Armstrong World Industries, Inc.  
 Artee Industries Inc.  
 Arvco Container Corporation  
 Ashby Cross Company  
 Ashland Oil, Inc.  
 Associated General Contractors  
 Associated Industries of Massachusetts  
 Associated Industries of Missouri  
 Associated Packaging, Inc.  
 Association of Concerned Taxpayers  
 Association of Container Reconditioners  
 Association of Home Appliance Manufacturers  
 AT&T  
 Atco Rubber Products, Inc.  
 Athens Plow Company, Inc.  
 Atkomatic Valve Company  
 Atlantic Marine Inc.  
 Atlantic Valve Corporation  
 Augers Unlimited, Inc.  
 Aulenback, Inc./Archie's Inc.  
 Azko Corporation  
 B F C Industries  
 B-P Products, Inc.  
 B. de Shell-Dome & Cie  
 B. Walter & Company, Inc.  
 Babson Brothers Company  
 Ball Corporation  
 Baltimore Gas & Electric Company  
 Bangor Hydro-Electric Company

Barber Manufacturing Company  
 Barney Machinery Company  
 Base 10, Incorporated  
 Batesville Products, Inc.  
 Bay City Platers  
 Beacon Plastics, Inc.  
 Bechdon Company, Inc.  
 Bekum America Corporation  
 Belton Industries Inc.  
 Benchmark Foam Inc.  
 Benda Tool & Model Works Inc.  
 Berner Cheese Corporation  
 Berns Brothers, Inc.  
 Besly Products Corporation  
 Beverly Manufacturing Corporation  
 Bigbee Steel Buildings Inc.  
 Bioanalytical Systems Inc.  
 Blazer Industries, Inc.  
 Bobo Engineering Inc.  
 Bonide Products, Inc.  
 Bootz Manufacturing Company  
 Boston Edison Company  
 Boston Steel & Manufacturing Company, Inc.  
 Bowater, Inc.  
 Boxes to Size, Inc.  
 BP America  
 Branch-Smith Inc.  
 Brick Institute of America  
 Briggs & Stratton Corporation  
 Brink's Home Security Inc.  
 Brockway Pressed Metals Inc.  
 Brown Galvanizing Company  
 Brown's Bakery Inc.  
 Buckingham Manufacturing Company  
 Buhler, Incorporated  
 Burroughs Wellcome Company  
 Business and Institutional Furniture Manufacturers  
 Business Council of NY State, Inc.  
 Byron Originals, Incorporated  
 C E C Controls Company, Inc.  
 C. R. Brophy Machine Works, Inc.  
 C. R. Hudgins Plating, Inc.  
 C. Warner Smith & Associates, Inc.  
 C. W. Maine & Sons

Calculagraph Company  
 Can Manufacturers Institute  
 Capital Veneer Works, Inc.  
 Capitol Manufacturing Company  
 Carbide Probes, Inc.  
 Carolina Power & Light Company  
 Cascade Corporation  
 Casket Shells, Inc.  
 Caterpillar Inc.  
 CBW Automation, Inc.  
 Celentano Bros. Inc.  
 CENEX Inc.  
 Centerior Energy Corporation  
 Central Hudson Gas & Electric Corporation  
 Central Illinois Steel Company  
 Central Louisiana Electric Company  
 Central Machine & Tool Company  
 Central Maine Power Company  
 Centrex Precision Plastics  
 Cerro Metal Products Company  
 Certified Metal Craft  
 CGR Products Inc.  
 Chain Supply Company  
 Charleston Hosiery, Inc.  
 Chemical Manufacturers Association  
 Chemtron Corporation  
 Cherry Lane Lithographing Corporation  
 Chevron Corporation  
 Chevron U.S.A. Inc.  
 Chicago Extruded Metals Company  
 Christy Refractories Company  
 Chrysler Corporation  
 CINergy Corporation  
 Circle Plastics Products  
 Cisneros Packing Company, Inc.  
 Clark Casual Furniture Inc.  
 Clark Container, Inc.  
 Clark Oil and Chemical Division  
 Cleveland-Cliffs Incorporated  
 Cleveland Foundry & Manufacturing Company  
 Clow Stamping Company  
 CMS Energy Corporation  
 Coalition for American Equity Expansion  
 Coalition for Responsible Waste Incineration

Coastal Lumber Company  
 Coastcom  
 Coen Company  
 Coil Specialty Company  
 Cole Screw Machine Products  
 Colorcraft Graphic Arts, Inc.  
 Coltec Industries Inc.  
 Communications Products Corporation  
 Computer and Communications Industry Association  
 Conklin Instrument Corporation  
 Conn-Weld Industries, Inc.  
 Consolidated Water Power Company  
 Consumers Power Company  
 Continental Mineral Processing Corporation  
 Contour Packaging, Inc.  
 Cook Sales Inc.  
 Cooley Incorporated  
 Coos Bay Fabrication & Machine Inc.  
 Copper and Brass Fabricators Council, Inc.  
 Correct Craft Inc.  
 Cosmo Oil of U.S.A., Inc.  
 Council for Citizens Against Government Waste  
 Crane Plastics Company  
 Cratex Manufacturing Company, Inc.  
 Cross Pointe Paper Corporation-Flambeau Mill  
 Crown City Plating Company  
 CSX Corporation  
 Curran Coil Spring Inc.  
 Custom Grinders Sales, Inc.  
 CVC Specialty Chemicals, Inc.  
 D/A Manufacturing Company, Inc.  
 D L H Industries Inc.  
 Dallas Container Corporation  
 Dana-Saad Company Inc.  
 Darling Store Fixtures  
 Davis Core & Pad Company<sup>6</sup>  
 Davis-Standard  
 Dayton-Granger Incorporated  
 Degussa Corporation  
 Delaware State Chamber of Commerce  
 Delmarva Power & Light Company  
 Delta Automotive, Inc.  
 Delta Systems Inc.

Delta Truss Incorporated  
 Dettra Flag Company Inc.  
 Diagraph Corporation  
 Dicey Mills Inc.  
 Die-Tech, Inc.  
 Diebold Incorporated  
 Diehl, Inc.  
 Diemasters Manufacturing, Inc.  
 Dilley Manufacturing Company  
 Dimco-Gray Company  
 Divine Brothers Company  
 Donisi Mirror Company  
 Doron Precision Systems, Inc.  
 Dorsey & Whitney  
 Downard Hydraulics Inc.  
 Downey Printing, Inc.  
 Drive Train Industries, Inc.  
 Drummond Company, Inc.  
 DSM Engineering Plastics  
 Du Pont Company  
 Duke Manufacturing Company  
 Duke Power Company  
 Duncan Enterprises  
 Dunkirk Radiator Corporation  
 Dymax Group, Inc.  
 E F P Corporation  
 E S Adkins & Company  
 E. W. Keith & Associates  
 Eastern Alloys, Inc.  
 Eastern Etching & Manufacturing Company  
 Eastern Utilities Associates  
 Eastman Chemical Company  
 Eastman Kodak Company  
 Eaton Corporation  
 Eaton Rapids  
 Echlin Inc.  
 ECOLAB, INC.  
 Edison Electric Institute  
 Egging Company  
 Eka Nobel Inc.  
 Electronic Industries Association  
 Elliott-Williams Company  
 Emerson Electric Company  
 Emmaus Area Chamber of Commerce

Employers Association, Inc.  
 Ener-G-Foods Inc.  
 Energy Shield Incorporated  
 Enserch Corporation  
 Ensign-Bickford Industries, Inc.  
 Entergy Corporation  
 Enting Water Conditioning, Inc.  
 Envelope Manufacturers Association of America  
 Environmental Coatings, Inc.  
 Environmental Compliance Services  
 Eva-Tone Inc.  
 Evans Box Manufacturing Corporation  
 Evans Industries, Incorporated  
 Excel Foundry and Machine, Inc.  
 Exxon Company U S A  
 Exxon Corporation  
 Eze Manufacturing Southeast  
 Faulhaber Company  
 Ferno-Washington Inc.  
 Fiberesin Industries, Inc.  
 Finnaren & Haley Inc.  
 Fisher Tank Company  
 Flexible Packaging Association  
 Flint River Mills  
 Florida Citrus Mutual  
 Florida Plywoods, Inc.  
 Florida Power Corporation  
 FLX Products Industries, Inc.  
 FMC Corporation  
 Fordsell Machine Products Company  
 FormPac Corporation  
 Forster-Long, Inc.  
 Fort Howard Corporation  
 Foster Canning, Inc.  
 Four Way Roofing, Inc.  
 Franklin Environmental Services  
 Freeman Manufacturing Company  
 Friftam Pumps  
 Frit, Inc.  
 Ft. Wayne Mold & Engineering  
 G M Nameplate Inc.  
 G T I Graphic Technology  
 G. J. Nikolas and Company, Inc.  
 G. W. Fiberglass Inc.

Gamco Industries, Inc.  
 Gardner Spring, Inc.  
 Garlinghouse Brothers Manufacturing Company  
 Gas Appliance Manufacturers Association  
 Gasket Materials Corporation  
 Gateway Press Inc.  
 Gauld Equipment Company  
 Geiger International, Inc.  
 Gemini Coatings, Incorporated  
 General Filters Inc.  
 General Motors Corporation  
 General Public Utilities Corporation  
 Geneva Steel, Inc.  
 Genie Trucking Line, Inc.  
 Georgia Gulf Corporation  
 Georgia Power Company  
 Gesmar Corporation  
 Gigante Associates, Ltd.  
 Gilmore Valve Company  
 Girard Industries, Incorporated  
 Glass Packaging Institute  
 Glover Machine Company  
 Golden's Foundry & Machine Company  
 Good Earth Tools, Inc.  
 Grainger Manufacturers Inc.  
 Grasan Equipment Company  
 Great Plains Ventures, Inc.  
 Griffin Environmental Company, Inc.  
 Griffith Rubber Mills  
 Grocery Manufacturers of America, Inc.  
 Grundy Industries Inc.  
 Gulf Power Company  
 H & R Plastics, Inc.  
 H. Meyer Dairy Company, Inc.  
 H. E. Anderson Company, Inc.  
 Hannay Reels  
 Harbison-Fischer, Inc.  
 Hardwood Manufacturers Association  
 Harsco Corporation  
 Hart Tie & Lumber Company, Inc.  
 Haysite Reinforced Plastics  
 Health Industry Manufacturers Association  
 Hearing Industries Association  
 Heatbath Corporation

Hecla Mining Company  
 Heinrich Envelope Inc.  
 Henry Filters, Inc.  
 Heritage Custom Fabricators Inc.  
 Hi-Tech Rubber, Inc.  
 Higbee Gaskets & Sealing Products  
 Hill & Associates, Inc.  
 Hiwassee Manufacturing Company, Inc.  
 HMC Technologies  
 Hodgdon Powder Company, Inc.  
 Hofmann Industries Inc.  
 Holt Hosiery Mills, Inc.  
 HON Industries  
 Honee Bear Canning Company  
 Hood Enterprises, Incorporated  
 Hooker Furniture Corporation  
 Hope Brick Works, Inc.  
 Horsehead Resource Development  
 House-Autry Mills Inc.  
 Houston Industries, Inc.  
 Hudson Screw Machine Products  
 Humco Holding Group, Inc.  
 Hutchens Industries, Inc.  
 Hyde Park Electronics, Inc.  
 Hydro-Hoist Company Inc.  
 Illinois Manufacturers' Association  
 Imperial Products Inc.  
 Indiana Manufacturers Association, Inc.  
 Indiana Michigan Power  
 Indiana Steel & Engineering  
 Industrial Brush Corporation  
 Industrial Ceramic Products, Inc.  
 Industrial Coating Inc. Steel Manufacturers Association  
 Industrial Safety Equipment Association  
 Industrial Wood Kraft, Inc.  
 Industry & Commerce Association of South Dakota  
 Inland Finishing Company  
 Innerpack of Carolina, Inc.  
 Institute for Regulatory Policy  
 Institute of Makers of Explosives  
 Interflo Technologies  
 International Dairy Foods Association  
 International Fabricare Institute  
 International Paper

International Sanitary Supply Association  
 Interstate pallet Company Inc.  
 Iowa Association of Business & Industry  
 Iowa-Illinois Gas & Electric Company  
 Ironbound Heat Treating Company  
 J & S Oil Company, Inc.  
 J & S Precision Products Company  
 J C M Industries, Inc.  
 JLG Industries, Inc.  
 Jogler Inc.  
 John Sterling Corporation  
 John W. Hancock Jr. Inc.  
 Johnson Electric Coil Company  
 Johnson Truck Bodies  
 Joseph E. Seagram & Sons, Inc.  
 JSJ Corporation  
 Jugs, Incorporated  
 K & D Heat Treat, Inc.  
 K-Products Incorporated  
 Kasper Manufacturing Company  
 Kaukauna Times Printing Company  
 Keip Machine Company  
 Kemlon Products  
 Kenfair Manufacturing Company  
 Kentucky Chemical Industry Council  
 Kester Solder Company  
 Kimple Mold Corporation  
 Kingston Metal Specialties  
 Kitchen Cabinet Manufacturers Association  
 Kiva Container Corporation  
 Klemco Eng., Inc.  
 Koch Industries, Inc.  
 Kohler Company  
 Kolene Corporation  
 Kona Corporation  
 Kopp Glass, Inc.  
 KRB/KlearKast  
 Kwik-File Inc.  
 Kysor Industrial Corporation  
 L D I Manufacturing Company, Inc.  
 L. B. White Company, Inc.  
 L. B. Plastics, Inc.  
 Laboratory Tops, Inc.  
 LaCroix Optical Company

Lake Region Manufacturing Company  
 Lane Plywood Inc.  
 Lead Industries Association  
 Lee Container Corporation  
 Leisters Furniture Inc.  
 Liberty Polyglas Inc.  
 Liberty Precision Tooling, Inc.  
 Lincoln Precision Machining Company  
 Linders Specialty Company, Inc.  
 Louisville Plate Glass Company  
 Luke Engineering & Manufacturing Company  
 Lukens Inc.  
 Lumber Tech, Inc.  
 Lumedyne Inc.  
 Lundell Manufacturing Corporation  
 MacDee, Inc.  
 Machtronic Products Company, Inc.  
 Mack Trucks Inc.  
 MacKenzie Manufacturing  
 Maclin Company  
 Magenta Corporation  
 Magic Novelty Company, Inc.  
 Magma Engineering Company  
 Malarkey Roofing Company  
 Management Partners, Inc.  
 Manrod Electric Inc.  
 Manufactured Housing Institute  
 Manufacturers Association of Central New York  
 Manufacturers Association of Mid-Eastern PA  
 Manufacturers Association of E. Ohio & W. Pennsylvania  
 Manufacturers Association of NW Pennsylvania  
 Manufacturers Association of Berks County  
 Manufacturing Systems, Inc.  
 Marco Company  
 Marisol Inc.  
 Mark VII Equipment Sales, Inc.  
 Marketing Resource Concepts, Inc.  
 Marley Mouldings, Inc.  
 Master Chemical Corporation  
 Master Manufacturers Inc.  
 Mathews Associates, Inc.  
 Matrix Unlimited, Inc.  
 Maxtron Corporation  
 Mayfair Mills

Maypak, Inc.  
 Maytag Corporation  
 McClarin Plastics Inc.  
 McElroy Manufacturing Inc.  
 McGard, Incorporated  
 McGee Industries Inc.  
 McKee Button Company  
 McShan Lumber Company  
 MD Chamber of Commerce  
 MDU Resources Group, Inc.  
 Medusa Cement Company  
 Melco Wire Products Company  
 Menasha Corporation  
 Menasha Poly Hi Solidur  
 Meridian Mattress Factory Inc.  
 Mertz Inc.  
 Metal-Fab Inc.  
 Metal Products Company  
 Metal Sales & Associates  
 Metal Treating Institute  
 Metropolitan Milwaukee Association of Commerce  
 Metzler Sales Company, Inc.  
 Meyers Printing Company  
 Michigan Chair Company, Inc.  
 Michigan Roll Form, Inc.  
 Microphor, Inc.  
 Mid City Plating Company Inc.  
 Midland Chicago Corporation  
 Midwest Industries, Inc.  
 Midwest Stamping & Manufacturing Company  
 Miller-Smith & Company  
 Milwaukee Crane  
 Minnesota Power Company  
 Mississippi Manufacturers Association  
 Mixer Systems Inc.  
 Mobay Road  
 Mobil Corporation  
 Modern Industries, Inc.  
 Molded Fiber Glass Companies  
 Montana Sulphur & Chemical Company  
 Monticello Hardwood, Inc.  
 Morrison Textile Machinery Company  
 Mother Truckers Supply  
 Mountain States Bindery

Mt. Carmel Public Utility Company  
 MTE Corporation  
 Multiplex Company, Inc.  
 Murphy Oil Corporation  
 Murphy Oil Corporation  
 N. H. Plastics  
 Nalco Chemical Company  
 Nasco Industries, Inc.  
 National Aggregates Association  
 National Association of Photographic Manufacturers  
 National Association of Manufacturers  
 National Association of Chemical Distributors  
 National Cement Company of CA  
 National Cigar Corporation  
 National Clay Pipe Institute  
 National Coal Association  
 National Electric Sign Association  
 National Electrical Manufacturers Association  
 National Environmental Policy Institute  
 National Food Processors Association  
 National Fruit Product Company, Inc.  
 National Glass Association  
 National Gypsum Company  
 National Housewares Manufacturers Association  
 National Industrial Sand Association  
 National Mower Company  
 National Ocean Industries Association  
 National Paint and Coatings Association  
 National Paperbox Association  
 National Petroleum Refiners Association  
 National Plating Company Inc.  
 National Purity Soap & Detergent  
 National Ready Mixed Concrete Association  
 National Screw Machine Products Association  
 National Starch & Chemical Company  
 National Taxpayers Union  
 Nebraska Chamber of Commerce & Industry  
 Nell Corporation  
 Nelson & Sons, Inc.  
 Nevada Power Company  
 New Jersey Rivet Company  
 New York State Electric & Gas Corporation  
 Newport News Shipbuilding  
 Niagara Mohawk Power Corporation

Non-Ferrous Founders' Society  
 Nooter Corporation  
 Norfolk Southern Corporation  
 North American Die Casting Association  
 North Metal & Chemical Company  
 Northeast Utilities  
 Northern States Power Company  
 Nuclear Energy Institute  
 Occidental Chemical Corporation  
 OHD Thermacore Inc.  
 Ohio Manufacturers' Association  
 Ohio Valley Steel Company Inc.  
 Ohio Willow Wood Company  
 Ohline Corporation  
 Olin Corporation  
 Olympic Limousine Service, Inc.  
 Orbit Valve Company  
 Oregon Steel Mills Inc.  
 Oryx Energy Company  
 Otto Engineering, Inc.  
 Outboard Marine Corporation  
 Owens-Corning Fiberglas Corporation  
 Ozark Wire Limited  
 PA Manufactured Housing Association  
 PACCAR Inc.  
 Pacific Metallurgical, Inc.  
 Paisley Farm, Inc.  
 Palm Sales, Inc.  
 Panhandle Eastern Corporation  
 Parfect Equipment Corporation  
 Paxton-Mitchell Company  
 Peabody Holding Company Inc.  
 Pearl Brewing Company  
 Pearl-Pressman-Liberty, Inc.  
 Pearson Candy Company  
 Peavey Electronics Corporation  
 PECO Energy Company  
 Pellerin Milnor Corporation  
 Pelron Corporation  
 Pennsylvania Manufacturers' Association  
 Pennsylvania Power & Light Company  
 Perfection Tool & Mold Corporation  
 Performance Alloys and Services, Inc.  
 Peterson Manufacturing Company

Petroleum Marketers Association of America  
 Pflow Industries, Inc.  
 Pharmachem Corporation  
 Pharr Yarns Of Georgia Inc.  
 Phelps Dodge Corporation  
 Philip Morris Companies Inc.  
 Phillips Manufacturing Company  
 Phillips Petroleum Company  
 Phoenix Foam Company  
 Physio-Control Corporation  
 PIAD Precision Casting Corporation  
 Piedmont Associated Industries  
 Pioneer Press, Inc.  
 Pittsburgh Spring, Inc.  
 Placon Corporation  
 Plain N Fancy Kitchens, Inc.  
 Plastinetics, Inc.  
 Plastinetics, Inc.  
 PMP Corporation  
 Pneudraulics Inc.  
 Polyfoam Corporation  
 Polyvend, Inc.  
 Portable Power Equipment Manufacturers Association  
 Powdercoat Services, Inc.  
 Power Transmission Distributors Association  
 Praegitzer Industries, Inc.  
 Praxair, Inc.  
 Precision Metal Spinning Company  
 Precision Metalforming Association  
 Prince Rubber & Plastics Company, Inc.  
 Procoaters, Inc.  
 Procter & Gamble Company  
 Products Finishing Magazine  
 Professional Positioners, Inc.  
 Progressive Tool & Industries Company  
 Protective Coatings, Inc.  
 Pruett-Schaffer Chemical Company  
 Public Service Electric & Gas Company  
 Puerto Rico Manufacturers Association  
 Puget Sound Power & Light Company  
 Q & D Plastics, Incorporated  
 Q S C Audio Products, Inc.  
 Quality Investment Castings, Inc.  
 R. E. Uptegraff Manufacturing Company

R. J. Levulis & Associates  
 R. P. Industries, Inc.  
 Radoll Designs, Inc.  
 Rainsoft Water Conditioning Company  
 Rapco Industries, Inc.  
 Raytheon Company  
 Raytheon Company  
 RCM Industries  
 Red Hill Hosiery Mills Inc.  
 Reid Petroleum Corporation  
 Reitech Corporation  
 Repro-Lon, Inc.  
 Republic Engineered Steels, Inc.  
 Resource Building Materials, Inc.  
 Reva Plastics Corporation  
 Rieter Corporation  
 Rinker Oil Corporation  
 Ripon Foods, Inc.  
 Riverside Energy, Inc. & Seaboard Tank Lines  
 Roberts Manufacturing Company  
 Robinson Brick Company  
 Robinson Dairy Inc.  
 Robinson Enterprises, Inc.  
 Rochester Gas & Electric Company  
 Rockford Process Control Inc.  
 Rockwell  
 Rohm and Haas Company  
 Root Spring Scraper Company  
 Rose City Manufacturing Company, Inc.  
 Row, Inc.  
 Royal Appliance Manufacturing  
 Rubber Manufacturers Association  
 Rudd Company, Inc.  
 Rugby Manufacturing Company  
 Rush Engine Remanufacturers  
 Ryder System, Inc.  
 S D S Lumber, Inc.  
 Safety-Kleen Corporation  
 Saint-Gobain Corporation  
 Savannah Electric and Power Company  
 SCANA Corporation  
 Scandic Springs, Inc.  
 Schaefer Machine Company Inc.  
 Schiffli Lace and Embroidery Manufacturers Association

Schuller International, Inc.  
 Schulze Tool & Die Company  
 Science First  
 Scientemp Corporation  
 Sealeze Corporation  
 Sealright Company Inc.  
 Selmax Corporation  
 Sensormatic Electronics Corporation  
 Servants, Inc.  
 Seymour Manufacturing Company, Inc.  
 Shanklin Corporation  
 Shape Corporation  
 Shelby Industries, Incorporate  
 Silver Users Association  
 Skagit Architectural Millwork  
 Snyder Manufacturing Company Ltd.  
 Society of Glass and Ceramic Decorators  
 Society of the Plastics Industry, Inc.  
 Sommer Products Company, Inc.  
 South Central Industries, Inc.  
 South Georgia Millworks, Inc.  
 Southern Alloy Corporation  
 Southern Aluminum & Brass Fdy.  
 Southern Champion Tray Company  
 Southern Electric International Inc.  
 Southern Nuclear Operating Company  
 Southern States Cooperative  
 Southwestern Illinois Industrial Association  
 Spec Tool Company  
 Special-Lite, Inc.  
 Specialty Castings Inc.  
 Specialty Screw Corporation, Inc.  
 Specialty Transport  
 Spir-it, Inc.  
 Spray Products Corporation  
 Spring Manufacturers Institute  
 Springville Manufacturing Company  
 Spudnik Equipment Company  
 St. Joseph Light & Power Company  
 St. Mary's Galvanizing Company  
 Stan-Blast Abrasives Company, Inc.  
 Standard Golf Company  
 Staodyn, Inc.  
 Star Trailers

Steel Manufacturers Association  
 Steel Service Center Institute  
 Steel Service Center Institute  
 Steel Shipping Container Institute  
 Sterling Factories, Inc.  
 Sterling Paper Corporation  
 Stevens Plating Works, Inc.  
 Storck Baking Company  
 Storopack, Inc.  
 Sturtevant, Inc.  
 Styrotek Inc.  
 Sub-Zero Freezer Company Inc.  
 Sun Company Inc.  
 Sunbelt insulation and Roofing Company  
 Superior Glass Fibers Inc.  
 Swan Manufacturing Company  
 Swanknit, Inc.  
 Sweco Products Inc.  
 Sybron International Corporation  
 Systems Dynamics Incorporated  
 T & S Machine & Tools  
 T L Herring & Company  
 T W Garner Food Company  
 Tal Technologies/TK-7 Products  
 Talk O'Texas Brands, Inc.  
 Tam Ceramics, Inc.  
 Tankcraft Corporation  
 Tech-Mark, Inc.  
 Technical Ordnance Inc.  
 Techno Adhesives Company  
 Teksid Aluminum Foundry, Inc.  
 Telect, Incorporated  
 Telpro, Inc.  
 Ten-Tec, Incorporated  
 Tenneco Inc  
 Texaco Inc  
 Texas Utilities Services Inc.  
 Textile Care Allied Trades Association  
 The Aluminum Association  
 The Belden Brick Company  
 The C. P. Hall Company  
 The Chlorine Institute, Inc.  
 The Clorox Company  
 The Daniel Weaver Company

The Detroit Edison Company  
 The Dexter Corporation  
 The Elge Spark Wheel Company  
 The Emmaus Area Chamber of Commerce  
 The Empire District Electric Company  
 The Employers' Association  
 The Garrett Group  
 The General Engineering Company  
 The Goodyear Tire & Rubber Company  
 The Hoving Group  
 The John Berger & Son Company  
 The Manitowoc Company, Inc.  
 The Master Products Company  
 The Nock & Son Company  
 The OilGear Company  
 The Ovid Bell Press, Inc.  
 The Perlick Company, Inc.  
 The Pfaltzgraff Company  
 The Protectoseal Company  
 The Refractories Institute  
 The Ridge Company  
 The Schundler Company  
 The Southern Company Services, Inc.  
 The Summit Pressed Brick and Tile  
 The Taylor-Winfield Corporation  
 The Timken Company  
 The Western Sugar Company  
 The Wise Company, Inc.  
 Theis Precision Steel Corporation  
 Thermal Ceramics Inc.  
 Thermal Designs, Inc.  
 Thermon Manufacturing Company  
 Thermoseal, Inc.  
 Thrasher & Associates  
 TI Group Inc.  
 Timney Manufacturing, Inc.  
 Titan Industries  
 TOMRAY, Inc.  
 Tool Chemical Company, Inc.  
 Tosca, Ltd.  
 Toy Manufacturers of America, Inc.  
 Transco Energy Company  
 TransTech, Inc.  
 Tray Pak Corporation

Trimblehouse Corporation  
 Tru-Fast Corporation  
 Truck Components Inc.  
 TRW Inc  
 Tucson Tallow Co., Inc.  
 Tulsa Rubber Company Inc.  
 Tulsa Winch, Inc.  
 Turck, Inc.  
 Tuway American Group  
 Tyson Foods Inc.  
 U F E Inc.  
 U.S. Business & Industrial Council  
 U.S. Chamber of Commerce  
 Ultra Mold Corporation  
 Union Electric Company  
 Unique Mould Makers Limited  
 Universal Leaf Tobacco Company, Inc.  
 Unocal Corporation  
 Upper Peninsula Power Company  
 USG Corporation  
 Uvonics Company, Incorporated  
 Val-Kro, Inc.  
 Val-Tex  
 Valcom, Incorporated  
 Valen Manufacturing Company  
 Valley Plating Works, Inc.  
 Valve Manufacturers Association of America  
 Vanguard Products Corporation  
 Victory Specialty Packaging, Inc.  
 Vie-Del Company  
 Viking Industries Incorporated  
 Viking Machine & Design, Inc.  
 Villaume Industries Inc.  
 Vimasco Corporation  
 Virginia Manufacturers Association  
 VIZ Manufacturing Company  
 Voith Hydro, Inc.  
 Vonco Products, Inc.  
 Vulcan Materials Company  
 W A Cleary Corporation  
 W. T. Storey, Inc.  
 W. A. Baum Company, Inc.  
 W. J. Turpish & Company, Inc.  
 W. R. Cobb Company

W. T. Storey Inc.  
 Waterman Industries, Inc.  
 WCC Industries, Inc.  
 WEAMCO Inc.  
 Weatherly Casting & Machine Company  
 Webco Industries, Inc.  
 Weiss Industries, Inc.  
 Weld Tooling Corporation  
 Wendricks Truss Company, Inc.  
 West Mark Tanks  
 West Tech Inc.  
 West Texas Printing Company  
 Western Connecticut Industrial Council, Inc.  
 Western Foam Inc.  
 Western Resources, Inc.  
 Westvaco Corporation  
 Weyerhaeuser Company  
 Whatley Sign Advertising, Inc.  
 Whirlwind, Inc.  
 White Instruments A Div. of C. Van R. Inc.  
 Wilkens-Anderson Company  
 Willamette Pattern Works Inc.  
 Williams Sound Corporation  
 Windmoeuer & Hoelscher Corporation  
 Windsor Homes, Inc.  
 Winnsboro Plywood Company, Inc.  
 Winters Foam Systems, Inc. Lundin Roofing Company Inc.  
 Wirebound Box Manufacturers Association  
 Wisconsin Electric Power Company  
 Wisconsin Manufacturers & Commerce  
 Wisconsin Metal Products Company  
 Wisconsin Power & Light Company  
 Wisconsin Public Service Corporation  
 Wisconsin Valley Concrete Products  
 Woerner Engineering, Inc.  
 Wright & McGill Company  
 WSF Industries, Incorporated  
 York Container Company  
 Yuasa-Exide, Inc.  
 Zaclon, Inc.

The CHAIRMAN. Thank you very much, and I assure you, your entire statement will be included in the record and we do thank you for the helpful nature of a lot of the specific suggestions that you make in that statement.

Our next witness will be Dr. John Graham, professor of policy and decision sciences, the Harvard Center for Risk Analysis.

Dr. Graham.

Mr. GRAHAM. Thank you very much. I appreciate the opportunity to be here.

The issue that is before us is the health and safety of the American people, the quality of our environment, and are we doing the best we can with the 200 or so billion dollars that we are spending every year on behalf of human health, safety, and the environment.

Let me begin by indicating that I am a very strong proponent of the general thrust of H.R. 9 and its key provision calling for more and better use of risk analysis by Federal regulatory agencies, new legislation can help in numerous ways, but I would like to highlight at the outset the two most important things this legislation does. One, it provides a statutory requirement that Federal agencies report realistic estimates of danger based upon the best available science.

We all know that each agency has an incentive to try to get all the resources they can and then hence has an incentive on occasion to highball the estimates of danger that are within the jurisdiction of their agency. This statute says we are all going to work from a level playing field on how we do the science of risk assessment.

Second of all, this legislation has a statutory requirement that regulators explain how their decisions reflect a relationship between the benefits of reducing danger to health, safety, and the environment and the costs and the unintended risks of those regulatory decisions. That is an explanation that we sorely need on many regulations.

Now you might ask, aren't Federal agencies—aren't they already doing this risk analysis you are talking about, Professor Graham? Don't we already have lots of risk analysis? And the answer is, this tool is currently used in the Federal Government but not in a very rigorous and systematic manner. Some protection decisions such as those involving pesticide registrations are informed by detailed, voluminous risk assessments while others are subject to no risk analysis whatsoever, and indeed it was Congress in some cases, such as in the Clean Air Act, that allowed EPA to run forward and do regulations without doing any risk analysis, and hopefully this bill will contribute to a new perspective on this issue.

In fact, it is interesting, the choice of regulatory priorities, which dangers, which risks do we worry about, that is rarely ever subjected to any significant analysis. EPA, for example, openly acknowledges today that its budgetary priorities are not in sync with the most serious environmental problems this country faces.

Former EPA administrator Bill Reilly was recently at Harvard, and he gave a very interesting, reflective talk on what happened when he was administrator at EPA, and with some pride he commented that he had increased the budget at EPA for high risk dangers from 15 percent of the budget to 30 percent of the budget, and

he hinted that maybe Congress could do better than that if they really want to focus on a risk-based approach to regulation.

Another example of this perversity, remarkably little analysis is devoted to identifying and quantifying the risks that are caused by Federal regulation, not just the risks that regulators hope to conquer but the risks that they create through regulation. For example, despite a Federal court order requiring full disclosure of all the consequences of regulation, the National Highway Traffic Safety Administration has still not, to the best my knowledge, produced a numerical estimate of how many motorists are killed or injured in car crashes each year because cars are now smaller and lighter due to the Federal Government's requirement that they be more fuel efficient. It is a difficult balancing judgment, but we are not even getting the information on the trade-off of safety and fuel economy into the regulatory process.

The scientific quality of the risk analyses produced by Federal agencies is uneven. In fact, some Federal agencies, such as the Environmental Protection Agency, conduct risk analyses in a very peculiar manner. For example, they stubbornly hold on to these so-called default assumptions even when scientific information is available that can provide a more realistic estimate of risk. When scientific information about risk is uncertain, some agencies are inclined to publish only a worst case estimate of how terrible the danger could be without giving any indication of what the most likely indication of risk would be.

The important practice of subjecting agency analyses to independent peer review by qualified experts is sporadic. Some agencies do it a lot—on this score EPA is often good—but other agencies often never have any independent peer review of their assessments.

An example of where EPA is not doing so well is the so-called Integrated Risk Information System, and if the members in this hearing do nothing after this hearing, I hope you will ask your staff what is IRIS? Why are people concerned about IRIS? IRIS is a computerized database that sends sensitive information on the toxicity of hundreds of chemicals all the way around the planet. This information is rarely peer reviewed. It is outside the protections of the Administrative Procedures Act, and a good bit of that information is flawed and outdated. It is something this committee needs to learn about and look into.

There are over 50 Federal agencies now operating to regulate the behavior of firms or private citizens and States and localities. Now the budgetary outlays of these agencies are modest, in total \$15 billion a year, but the economic impacts of their decisions extend far beyond the Federal budget. For example, as the previous witness noted, economists estimate the rules issued by these agencies cost the country \$580 billion a year. That is about \$6,000 per household. Various health, safety, and environmental regulations are responsible for the majority of this economic burden.

Now it is interesting, the fastest growing sector of these risk protection expenditures are environmental regulation. It is now growing at a larger annual rate than the health care industry in this country. If Congress does not take action soon on environmental regulation, we will soon have a crisis in environmental spending similar to what we now face in health care.

For years I have urged Federal agencies to practice sound risk analysis on the theory that they would be persuaded by the logic and by good science. Frankly, only limited progress has been made over these years. If Congress does not pass legislation, it will be a clear signal to regulators that business as usual is appropriate even under the new political regime that we are now under. From both a public health and an economic perspective, I urge you to consider a new signal to these agencies.

To illustrate this opportunity, I would like to quote the findings of Tammy Tengs, a doctoral student of mine in her thesis, where she analyzed 500 life-saving programs in the United States, and she did the following calculation. If we were to reallocate resources from the expensive and wasteful programs and allocate it on the more promising and effective programs, we could save 60,000 lives per year in this country, save 600,000 additional years of life for the American citizens, all of this at no increased cost to the American taxpayer or to the private sector of the economy.

If we fail to pass H.R. 9 and thereby ignore these life-saving opportunities, I submit to you that our children will have a right to accuse us of engaging in what I call statistical murder. Statistical murder is when you don't do risk analysis, you spend your money on the small risks, and you let the big killers go free. That, I think, is what this legislation is about.

Thank you very much.

[The prepared statement of Mr. Graham follows:]

WRITTEN TESTIMONY OF JOHN D. GRAHAM, Ph.D.\*  
HARVARD SCHOOL OF PUBLIC HEALTH

"Risk Assessment and Cost-Benefit Analysis of New Regulations"

Title III, H.R. 9, 104th Congress, First Session

January 31, 1995: Hearings Before the House Science Committee

February 2, 1995: Hearings Before the House Commerce Committee  
Washington, D.C.

\* For a copy of the technical Appendix to this testimony, write Ellen Patterson,  
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02115 (617)432-4497.

My name is John D. Graham. I am Professor of Policy and Decision Sciences at the Harvard University School of Public Health and founding Director of the Harvard Center for Risk Analysis. I am also President-Elect of the Society for Risk Analysis (SRA), an international scientific society of risk analysts from government, business, and academia. The remarks contained herein should be attributed to me and should not be attributed to Harvard University or SRA.

Let me begin by indicating that I am a strong proponent of the general thrust of H.R. 9 and its key provisions calling for more and better use of risk analysis by federal regulatory agencies. New legislation can help in numerous ways but the two most urgent needs are (1) a statutory requirement that federal agencies report realistic estimates of risk based on the best available science, and (2) a statutory requirement that regulators explain how their decisions reflect a reasonable balance between the benefits of reducing risk and the costs (and unintended risks) of regulation.

I applaud the bipartisan coalition of legislators who have been working for more than a year to refine, sharpen, and improve the legislation that we are discussing today. I am also pleased that the Clinton Administration has begun to take a more constructive posture toward this legislative initiative.

My testimony is aimed at clarifying why legislation is necessary and why the arguments raised against H.R. 9 are not compelling. In fact, most of the arguments that have been raised publicly against risk analysis reflect a misunderstanding of this relatively young but rapidly developing field.

"Risk analysis" is a broad term used to refer to a variety of analytical tools and processes including risk assessment, risk characterization, comparative risk assessment, risk ranking, risk-based priorities, risk-benefit analysis, benefit-cost analysis, risk equity, risk management, and risk communication. Although there are important and subtle differences in the meanings of these terms, the legislation under consideration addresses all of them to various degrees.

## THE RATIONALE FOR RISK ANALYSIS

Each day Americans are confronted with new information about potential dangers to their health and safety: childhood leukemia from exposure to electric and magnetic fields, male infertility from exposure to chlorinated chemicals, brain cancer from using cellular telephones, subtle neurologic effects in children who ingest house dust contaminated with lead paint, breast cancer from consuming fruits and vegetables with minute amounts of pesticide residues, non-Hodgkin's lymphoma from farmworker exposure to phenoxy herbicides in agriculture, premature death among the elderly from inhaling fine particles in outdoor air, aggravation of asthma from breathing smog in urban areas, heart disease from eating margarine and other sources of trans-fatty acid, nausea from exposure to MTBE in regions where reformulated gasoline is used, and lung cancer from exposure to environmental tobacco smoke.

News stories about these alleged dangers populate both the electronic and print media. In fact, there is a tendency for reporters to give special attention to potential hazards that are "new," unfamiliar, invisible, frightening, bizarre and mysterious. Less attention is given to more "routine" -- yet widespread and deadly -- hazards such as acute injury from motor vehicle crashes, falls, drownings, and violence in our homes and communities. Thus, we should not expect that the public and our elected officials have a sound understanding of which threats are real and which are speculative or exaggerated, which are large and which are small, and which can be reduced or eliminated altogether through cost-effective actions.

The purpose of risk analysis is to provide such information (including indications of how much confidence to place in the information) in a form that is useful to decision makers in both the public and private sectors of the economy. When this information is placed in a relative context (e.g., comparing one risk in life to another), it can be useful in helping people decide which dangers deserve the highest priority and which can be safely ignored until better information is available.

Risk analysis is particularly useful for decision makers, such as federal regulators, who are often compelled by law or good judgement, to take protective actions before an alleged hazard has been documented by science with 100% certainty. For example, the decision by EPA in the early 1980's to phase-out the use of lead in gasoline was motivated not by popular opinion, media campaigns, or environmental advocacy groups but by a careful benefit-cost analysis of the issue.

## DEFICIENCIES IN THE FEDERAL GOVERNMENT'S CURRENT SYSTEM

The tools of risk analysis are currently used by the federal government but not in a very rigorous and systematic manner. Some protection decisions are informed by detailed risk analyses while others are subject to no analysis whatsoever. For example, pesticide manufacturers are required by EPA to supply voluminous analyses in support of registration decisions while EPA no longer performs any risk analysis when issuing technology-based regulations of industrial facilities under Title III of the Clean Air Act Amendments of 1990. The basic problem is that Congress has never embraced the fundamental principle that all regulatory decisions should be influenced by a consideration of risk, benefit, and cost.

In fact, the choice of regulatory priorities is rarely informed by formal analysis. EPA, for example, now openly acknowledges that its budgetary priorities are not in synch with the seriousness of risks and only modest reallocations from overblown (e.g., pesticide residues) to neglected (e.g., indoor air pollution) dangers have occurred since EPA acknowledged this perversity in 1987. Former EPA Administrator William Reilly commented in a recent speech at Harvard that the fraction of EPA's budget devoted to "high-risk" threats increased from 15% to 30% during his four-year tenure at EPA. Not surprisingly, he hinted that Congress needs to give more emphasis to the need for risk-based priorities in budgeting and regulation.

Remarkably little analysis is devoted to identifying and quantifying the risks caused by

federal regulation! The "target risks" discussed in the media often become a preoccupation of federal agencies while the "countervailing risks" induced by regulation are ignored altogether. For example, despite a federal court order requiring full disclosure of regulatory consequences, the National Highway Traffic Safety Administration has still not produced a numerical estimate of the number of motorists killed or injured each year due to the Corporate Average Fuel Economy (CAFE) Program, a well-intended "energy conservation" rule that induces vehicle manufacturers to produce smaller and lighter cars than consumers would normally demand.

The scientific quality of the risk analyses produced by federal agencies is uneven. In fact, some federal agencies, such as the Environmental Protection Agency, conduct risk analyses in a very peculiar manner. They appear stubborn about maintaining various "default assumptions" and consequently do not make good use of new scientific information. When scientific information about risk is uncertain, some agencies are inclined to publish "worst-case" estimates of risk without providing any realistic indication of what the actual risk is likely to be. In other situations, some agencies have neglected to assess the impact of hazards on highly exposed or susceptible subpopulations of citizens.

The estimates of risk reported by different federal agencies are not always consistent, even when the same data on the same chemical are being assessed (e.g., dioxin, butadiene, benzene, and formaldehyde). There is no justification for such technical discrepancies in the different statutory mandates that govern the risk assessment practices of these agencies. EPA, OSHA, and FDA often differ in their assessments of chemical carcinogens while EPA and NRC often differ in their assessments of radiation risks. Some recent efforts have been made to harmonize agency practices but discrepancies remain (as evidenced by the recent disagreements between EPA and FDA scientists about the risks of low levels of exposure to dioxin).

The important practice of subjecting agency analyses to independent peer review by qualified experts is sporadic in some agencies and absent entirely in other agencies. Speculative estimates of regulatory cost are often subjected to no peer review while epidemiological or toxicological estimates of risk are sometimes subjected to extensive review. OSHA, in particular, has a poor track record in the use of independent panels of peer reviewers.

The opportunity for the public, including affected stakeholders, to offer comment on agency analyses is not always provided, particularly when an agency decides to publish the assessment without pursuing a formal rulemaking. Since the mere publication of a risk assessment report -- which may include provocative designations such as "carcinogen" and "neurotoxin" -- can create big winners and losers in our global economy, a responsible system of checks and balances must be built into the entire process of risk analysis -- even if a formal agency rulemaking is never initiated. For example, EPA's Integrated Risk Information System (IRIS) provides sensitive toxicity information on hundreds of chemicals to citizens, firms, and governments throughout the world, yet IRIS operates completely outside the notice-and-comment protections of the Administrative Procedures Act.

## BIG STAKES: PUBLIC HEALTH AND ECONOMIC WELL-BEING

The case for comprehensive risk analysis legislation is strengthened when we consider the stakes involved for this country.

While America has made steady progress since World War II in reducing dangers to human health, safety, and the environment, more progress is urgently needed. For example, the United States does not rank in the top twenty countries in the world in life expectancy at birth, one of the most fundamental public health statistics. Even at age 65, our nation's ranking in life expectancy is still not in the top ten of countries around the world. This information suggests that if the U.S. targets its resources at well-documented and important hazards, substantial gains in public health are feasible.

There are over 50 federal agencies now operating to regulate the behavior of firms, private citizens, and states and localities. Although the budgetary outlays of these agencies are a modest \$15 billion per year, the economic impacts of their decisions extend far beyond the federal budget. For example, economists estimate that the rules issued by these agencies cost the country \$580 billion per year, or almost \$6,000 per household. Various health, safety and environmental regulations are responsible for the majority of this economic burden. The fastest growing sector of risk-protection expenditures, environmental regulation, is now growing at a larger annual rate than the health care industry. If Congress does not take action soon, we will soon have a crisis in environmental spending similar to what we now face in health care!

## DIRECTIONS FOR LEGISLATIVE ACTION

In a recent paper commissioned by the American Enterprise Institute (attached), I described in some detail the principles that should govern legislative reform: RESPONSIBLE RISK ASSESSMENTS, RISK-BASED PRIORITY-SETTING, REPORTING RISKS, BENEFITS, AND COSTS, REASONABLE RELATIONSHIP BETWEEN COST AND RISK REDUCTION, EXTERNAL MECHANISMS OF SCIENTIFIC PEER REVIEW, JUDICIAL REVIEW UNDER A PRINCIPLE OF DEFERENCE, and ANALYTICAL RESOURCES. The provisions in H.R. 9 are broadly consistent with these principles. Rather than repeat these points here, I have simply attached the AEI paper to this testimony as an Appendix for those who want more details and supporting references to the scientific literature. Here I would simply like to emphasize three areas where H.R. 9 could be strengthened.

First, there is a need to mandate broad-based rankings of health, safety and environmental risks that cut across the jurisdictions of existing agencies. Such rankings could help inform the budgetary allocations of Congress and OMB. For example, the annual budget of U.S. EPA is more than three times larger than the annual budget of the Food and Drug Administration, yet I know of no comparative risk analysis that supports such a large discrepancy in budgetary priority. In order to make sure that such sweeping comparisons are made in a way that is responsive to science and citizen values, I recommend that the National Science Foundation be commissioned to undertake a two-year demonstration of prototype risk-

ranking procedures. The lessons from this demonstration could then be incorporated into periodic government-wide, risk-ranking exercises. Senator Daniel Patrick Moynihan (D-NY) has given serious consideration to these issues and should be consulted in developing precise legislative language on priority setting.

Second, there is a need to make sure that the findings of benefit-cost analyses are actually used by federal agencies when making specific rulemaking decisions. Where existing risk-protection statutes discourage or prohibit benefit-cost considerations, they should be overridden by H.R. 9. Otherwise, regulators will be inclined to ignore the results of benefit-cost analyses by hiding behind the provisions of existing law. Representatives Gary Condit (D-CA), Karen Thurman (D-FA), Pete Geren (D-TX) and John Mica (R-FA) have given serious thought to this issue and should be consulted when developing precise legislative language on how to incorporate benefit-cost considerations into the existing legal framework for risk regulation.

Third, the capacity of the Executive Office of the President to exercise leadership in risk analysis needs to be strengthened by legislative authorization and resources. In particular, no significant risk assessment should be published by a federal agency without the opportunity for review by an interagency panel of experts under the leadership of EOP. For example, any attempt by EPA to declare electric and magnetic fields a "carcinogen" should be submitted to EOP for review and approval. (Such review would be particularly useful in avoiding interagency discrepancies that have historically been a source of embarrassment to the United States in international negotiations.) Reasonable people disagree about precisely how this realignment of power in the federal government should be accomplished. Some say the Office of Management and Budget's capabilities should be buttressed while others say the Office of Science and Technology Policy should play a larger role. I would take a slightly different approach. In my opinion, a new 3-member Council of Risk Analysts, modeled after the Council of Economic Advisors, should be created in EOP to lead the executive branch's efforts in risk analysis. The chair and two members of CRA would be appointed by the President and confirmed by the Senate. These qualified and accountable presidential appointees should be assisted by a staff of career risk analysts from line agencies and OMB, perhaps in a manner somewhat similar to that recommended by Supreme Court Justice Stephen Breyer.

Finally, more thought needs to be given to whether the universities in this country are providing professionals and scientists with appropriate training in risk analysis to meet the demands likely to be generated by this legislation. It would be wise for Congress to authorize NSF or the National Academy of Sciences to assess the current state of university training and research in this area and make appropriate recommendations regarding needed innovation in curricula and research priorities. Congressman Richard Zimmer (R-NJ) has some excellent ideas on this point that could be readily added to H.R. 9.

## DUBIOUS OBJECTIONS TO RISK ANALYSIS

Strengthening the role of risk analysis is a threat to traditional power centers in Washington, D.C. that have controlled the agendas of regulatory agencies. Before the

congressional debate is over, we can safely predict that risk analysis will be the target of a heavy dose of "negative ads."

**MYTH #1: RISK ANALYSIS IS AN EVIL FRONT FOR INTEREST GROUPS WHO WANT TO ENDANGER PUBLIC HEALTH, SAFETY, AND THE ENVIRONMENT.**

In all broad-based political movements, the motives of those who support reform are diverse and not always transparent. We should judge a legislative proposal to promote risk analysis on the basis of whether its likely consequences are promising and avoid the temptation to discern and judge the motives of others.

**MYTH #2: RISK ANALYSIS NEVER SUPPORTS REGULATION.**

The following regulations, adopted in the 1980s, were each supported by various forms of risk analysis: the accelerated phase-out of lead in gasoline (EPA), the mandatory phase-out of chlorinated compounds with significant potential to deplete the stratospheric ozone layer (EPA), a new permissible exposure limit protecting workers from disease caused by exposure to cotton dust (OSHA), certain safety limitations on the sale and use of all-terrain vehicles (CPSC), and the requirement that all new vehicles be equipped with automobile airbags (NHTSA). They were adopted over the objections of powerful interest groups because a sound analytical case was made in their favor. If risk analyses do not provide much support for a regulatory proposal, we should be skeptical about whether the proposal is a good idea.

**MYTH #3: POLLUTION PREVENTION IS A BETTER IDEA THAN RISK ANALYSIS.**

Pollution prevention and risk analysis are complementary concepts. Without risk analysis, we won't know which pollutants or sources of pollutants should be required or induced to engage in prevention activities. If significant risks are measured now or forecasted to occur in the future, it certainly makes sense to explore pollution prevention opportunities. Like all other measures, proposals to "prevent pollution" should be evaluated to determine whether they reduce risk at a reasonable cost compared to alternatives.

**MYTH #4: IT IS TECHNICALLY IMPOSSIBLE AND UNETHICAL TO APPLY BENEFIT-COST ANALYSIS TO HEALTH, SAFETY, AND ENVIRONMENTAL PROBLEMS.**

Nonsense. Each spring I teach at the Harvard School of Public Health a 16-session graduate course on how to do what is supposedly impossible and unethical. The basic principle of the course is that government should provide risk protection to citizens if those who benefit would judge themselves better off, even if they incurred the cost of providing the risk protection -- Not a bad principle, particularly in this age of concern about "unfunded mandates!" It is technically feasible to place reasonable ranges of monetary values on health and ecological consequences and, where it is not possible to do so, tools of sensitivity analysis can be used to

allow the analyst to proceed forward. Benefit-cost analysis has a strong foundation in utilitarian ethics. Modern practitioners of the tool are well aware that in some cases non-utilitarian ethics (e.g., a concern for the welfare of the poor) may justify departure from the prescriptions of a strict benefit-cost analysis. Nothing in H.R. 9 would prevent a decision maker from considering both utilitarian and nonutilitarian ethical principles in reaching a final regulatory decision.

## CONCLUSION

For years I urged federal agencies to practice sound risk analysis on the theory that they would be persuaded by logic and good science. Only limited progress has been made. If Congress does not pass legislation, it will be a clear signal to regulatory agencies that "business as usual" is appropriate. From both a public health and economic perspective, our country can do much better with our regulatory resources.

To illustrate this opportunity, consider the recent finding of Dr. Tammy Tengs, a former Harvard doctoral student who recently joined the faculty at Duke University Medical School. In an imaginative analysis of 500 lifesaving programs in the United States, she found that a reallocation of resources from wasteful to efficient programs could save 60,000 lives and 600,000 life years annually at no increased cost to citizens<sup>7</sup>! If we fail to pass H.R. 9 and thereby ignore these lifesaving opportunities, our children we will have a right to accuse of us a shocking display of "statistical murder."

Thank you very much for the opportunity to testify today and please don't hesitate to contact me if you should desire further information or comment.

The CHAIRMAN. Thank you very much, Dr. Graham.

Our next witness is Mr. Gordon Garner, executive director of the Louisville and Jefferson County Metropolitan Sewer District, and it is my understanding that Mr. Ward would like to have a moment to introduce his constituent.

Mr. Ward.

Mr. WARD. Yes.

Good morning, and thank you, Mr. Chairman. I am delighted to have the opportunity to introduce my good friend, Gordon Garner. I assured him that even though he was here as a majority witness I was delighted to introduce him. That is especially true because my wife was chief counsel for the Metropolitan Sewer District for a number of years and had a wonderful relationship there and to this day misses her friends and coworkers.

Gordon Garner has had a distinguished career for over 26 years in the public sector, 21 years of which have been in the area of public works. He is active in many associations and groups and serves as the chair of the public policy—excuse me—the Public Advisory Committee for Kentucky Outlook 2000. It is a cooperative project involving the Kentucky Natural Resources and Environmental Protection Cabinet and the Kentucky Long-Term Policy Research Center. The project is working toward dealing with the kinds of problems that we are discussing today, and I think we will all benefit from Mr. Garner's testimony.

The CHAIRMAN. Thank you very much, Mr. Ward.

Mr. Garner, you come to us highly recommended. We welcome your testimony.

Mr. GARNER. Thank you, Mr. Chairman, members of the committee. I really am pleased to have the opportunity to be here today to talk about ways that environmental policy can be more reasonably and effectively implemented.

I am, it seems, the odd duck on the panel, representing State and local government, so I will try to hold my turf but, I do believe that this is an issue that we share a lot with the private sector. My agency, for example, regulates and serves 4,000 industries and businesses in the Louisville metropolitan area, so we are as both a regulator and a permitted industry—we have to deal with environmental regulation and translate it both for our business community and for the general public.

I think one of the things that's important for this committee to deal with in the long term on this issue is not to forget why we are talking about environmental risk. The main reason is that public outrage has been fueling a lot of the environmental regulations that have come about. A lot of the public outrage has been because the public has been dealing with perceived rather than real risk, involuntary risk—that is, risks that they are subjected to that they feel like they can't control, and risks that are close to their homes. Our risk assessments have been put forward to them in terms of cancer risks per million.

I can tell you as the vice chairman of the State Environmental Quality Commission, when we are dealing with environmental regulations, that the public does not want to hear about cancer risks in any way, shape, or form. So if we are going to translate risk assessments in a way that can be effective to this committee and to

Congress in making decisions about legislation, we have to avoid some of the dangers of the language and terminology associated with risk assessment.

State and local government has an interest in risk assessment because we have experienced environmental regulations in a manner that has at this point become rather overwhelming to us. Clearly we can't talk about our interest in risk assessment without pairing it with unfunded mandates, which you all are dealing with, I won't belabor that point, but the fueling factors of our interest are the funding issues, priority setting, and the breakdown of the Federal, State, and local partnership.

In the environmental arena, the State and local governments have become part of the regulated community. No longer are we partners with the Federal Government as we once were in trying to implement environmental laws and regulations, we are treated like the regulated community, and thus we have lost part of our involvement in the process of developing environmental laws and regulations and working with the Federal Government to see that they are reasonable and implementable. A lot of environmental laws have been criminalized, in fact all of them have, to the extent that they are in fact increasing the cost of implementation because of the severe penalties associated with even minor paperwork violations of environmental laws.

Environmental cleanup used to be a lot easier. The targets were visible, they were gross, and they were readily fixed with available technology. We are now dealing with environmental cleanup of things that are measured in parts per quadrillion and national debate raging about environmental cleanup on issues where the chemicals are below the detection limits of our current technology.

We have got to be smarter. Our approach to environmental problems needs to be targeted to address the real environmental problems that exist in a particular place. I applaud EPA's new place-based and common sense initiatives. I think this is a way that we might be able to work out some of the problems that we have due to conflicting and confounding environmental regulations that we are faced with.

The watershed approach in dealing with water quality problems is one example where we can look at a watershed and decide what the real problems are in a watershed and spend our money addressing the real problems instead of complying with a hundred or so different programs that might apply in that same watershed.

The Federal resources that are available should be used to assist State and local governments to set better priorities and to establish monitoring programs that measure real progress in protecting the environment, not just in submitting the paperwork and meeting the paperwork requirements.

I support the Risk Assessment and Communication Act. I think it is a very logical thing for us to do. Any legislation that is being considered should be justified on the merits, and having good factual information to make decisions is something that should be standard. We certainly try to do that at the State and local level.

There are a couple of things I would urge you to beware of. One, I would encourage you not to make risk assessment subject of judicial review. You will find that putting science in the courtroom is

never going to be a good solution to resolving our problems with environmental regulation.

The other thing is that we will never have certainty on risk assessments, it is just not the nature of the beast, so we should be careful that risk assessments are not used as a weapon to delay or thwart the legislative process or to clog up the courtrooms. Instead, they need to be a tool to inform and facilitate good decision making.

Risk assessments also need to be based on available resources and the best information that the agencies can find, recognizing that element of uncertainty. You are never going to have risk assessments that are going to answer everyone's questions or concerns.

Finally, realize that risk assessments do not cover all the bases. They do not provide a good means for dealing with the natural environment. If we are going to deal effectively with environmental regulation and deal with it fairly, we have got to recognize that we undervalue the natural environment in the way that we do our business, and if we do cost-benefit assessments of all of our regulation and use that as the sole basis to make decisions on environmental law, we will not succeed, we will be leaving out a critical element. So risk assessment should not be inappropriately used to undervalue natural systems and to thwart legitimate environmental regulation that may protect the natural environment.

Finally, keep in mind that high risk can usually be lowered by reasonable efforts. Zero risk cannot always be achieved at any cost. Some of our worse environmental sins are the result of avoiding or deferring actions that would lower risks through reasonable efforts. I would use for the most part the Clean Air Act deferral through the 1980's as an example of that. We avoided doing some things we should do.

But I can also tell you that some of the worst case scenarios that have been used by a few here this morning as examples are created by laws and regulations that are overreaching toward zero risks that cannot be achieved. In between it is our challenge to decide what risks are acceptable and what risks can be reduced or eliminated, and good information is required by this bill that you are considering will help us make these decisions better.

Thank you.

[The prepared statement of Mr. Garner follows:]

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**TESTIMONY BEFORE THE  
U.S. HOUSE OF REPRESENTATIVES**

**COMMITTEE ON SCIENCE**

**RISK ASSESSMENT AND COST/BENEFIT ANALYSIS**

Gordon R. Garner  
Executive Director

Tuesday, January 31, 1995

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## RISK ASSESSMENT AND COMMUNICATION

Mr. Chairman, members of the Committee, thank you for the opportunity to speak before you today as you consider the risk assessment title of HR9, a piece of the "Contract With America". I am Gordon Garner, Executive Director of the Louisville and Jefferson County Metropolitan Sewer District. MSD is a regional wastewater and stormwater utility serving the City of Louisville, unincorporated Jefferson County and 90 incorporated cities. MSD is the primary agency for implementing the Clean Water Act in our area. As a local government official, I am particularly pleased to discuss ways that environmental policy can be more reasonably and effectively implemented.

Risk assessment is an imprecise process. Whose risk is it? Do I have a choice? Who pays to reduce the risk? Risk of what?

Risk can be characterized in different ways:

Real risk.....	Perceived risk
Short-term risk.....	Long-term risk
Voluntary risk.....	Involuntary risk
Visible risk.....	Invisible risk
Risk to people.....	Risk to plants and animals

Using risk assessment as a tool to make enlightened decisions about legislation can be helpful if it is done objectively understanding that risk assessment is a tool, not a weapon!

It is also important not to forget public outrage at risks that are perceived, involuntary, and close to their homes -- no matter how inconsequential the risk may be by risk assessment criteria. If risk assessment is used to make decisions, the communications aspect is critical. Cancer risk per million has been demonstrated to be a very poor means of communicating risk to the general public.

Risk assessment has been viewed by some as a mechanism to derail meritorious environmental initiatives, particularly as part of the "holy trinity", which also includes unfunded mandates and private property rights. Others believe that risk assessment can limit environmental regulations to risks that meet some arbitrary career-risk threshold. In my opinion, neither view is correct. I believe the Risk Assessment and Communication Act of 1995 provides a mechanism for better priority-setting consistent with efforts being made by state and local governments across the country and with efforts already being used by some federal agencies, but not required by law.

The key forces that fuel state and local government support for the risk assessment and unfunded mandate bills are:

- Funding
- Priority setting
- Breakdown of Federal/State/Local Partnership

State and local governments have experienced a significant and continuing reduction in federal funding for basic infrastructure. This has been well documented. As federal contributions are reduced, it becomes more important to establish priorities and use available funds in the most cost-effective manner. Many federal programs come in a "one size fits all" package that prevents effective priority-setting at the state and local level. What was a partnership relationship to achieve national goals, has evolved into a much harder-edged enforcement/compliance driven relationship where state and local officials are treated as the "regulated community". "Command and control" is the operative lingo for what we have been experiencing. Instead of a government partnership to address problems, too often the issues are resolved (or deferred) through protracted and expensive litigation.

Federal environmental programs are often fragmented and uncoordinated. Lack of federal and state implementation resources sometimes results in local governments being legally liable for compliance (due to the establishment of unrealistic deadlines) -- often before the program guidance is written that defines what compliance is supposed to be. An example of this is the NPDES Stormwater Program. We have criminalized all environmental laws, thus increasing the cost to implement the laws. Many activities are criminalized that should not be. For example, a criminal violation can occur for reporting violations that do not put the environment at risk in any way. Regulations and guidance documents are often developed with inadequate state and local involvement. Local and state government paperwork compliance costs can sometimes exceed the cost to do what is needed to comply. The federal interests often go far beyond what the Federal government can or should legitimately do -- i.e., focus on issues of national concern.

The most successful environmental programs have been built on a foundation that recognized a partnership between federal, state and local government, usually with some cost-sharing by all. When everyone has dollars on the table, they are much more likely to discuss the issues, set priorities and reach consensus on the best approach and use of available funds. If a funding partnership does not exist, it is still possible to reach consensus through the negotiated regulations process... if all parties at the table are committed to reaching consensus. EPA has had success with this "reg/neg" process, most recently in the process establishing a national combined sewer overflow policy.

Environmental cleanup targets used to be easier to find... grosser, more visible and readily fixable using available technology. Now we are detecting and trying to abate chemical contamination that is measured in parts per quadrillion and in some cases, is below the detection limits of our current technology. The causes of pollution are diverse and the impacts at the state and local level may vary significantly. "One size fits all" is no longer an effective means of addressing all environmental problems. Science issues get politicized and positions are taken on national legislation based on unique circumstances of a city, state, or region -- usually highlighting the worse case scenario. The strongest advocates, both for and against environmental legislation are notorious for using worst case scenarios and often use factually incorrect information to support their positions.

We must be smarter in the future. Our approach to environmental problems needs to be targeted to address the real environmental problems that exist in a particular place. EPA's new place-based and common sense initiatives are to be encouraged. For example, the watershed approach to water quality is one example of a way we can better target available resources. Some urban streams may never be fishable (if eatable fish is the criteria) and swimmable (without risk) as long as we have pets, use lawn chemicals by the megatons and tolerate a high level of pollution from automobile use. The public must be involved in the cleanup of urban streams in a manner that could dramatically affect their lifestyle choices and pocket books. This cannot be mandated, but can only come about if the public "buys in".

Federal resources should be allocated to assist state and local governments to set better priorities and establish monitoring programs to measure real progress in protecting the environment. Federal resources are also needed to set standards for large industries or take on well-documented environmental problems that cannot be addressed effectively at the state and local level. (Examples -- regulation of pesticides and herbicides, large industries such as oil, metal plating, pulp and paper mills, energy utilities, etc.). The federal government should also address significant boundary issues between cities, states and other countries and international environmental issues of global concern.

Title III of HR9, The Risk Assessment and Communication Act, is just one piece of the solution puzzle. It requires that a baseline level of information be available when national legislation is being considered. It should be supported. Efforts to twist the intent and the effect of the legislation and should be avoided. For example, risk assessments should never be the subject of judicial review. Risk assessments that are done for controversial legislation will usually be challenged at both ends, often by credible scientists. It is an imprecise process. Certainty may be desired, but it is unachievable. Thus, risk assessments should not be used as a weapon to delay or thwart the legislative process, or to clog up courtrooms. Risk assessments should be a tool to inform and facilitate good decision making.

It also needs to be recognized that in many areas we know less than we should. We are not able to define every risk. Therefore, risk assessments must be based on available resources and the best information the agencies can find, recognizing that there is an element of uncertainty in the risk assessment process.

Of greatest concern is recognizing the limitations of risk assessment for dealing with the natural environment. The natural environment does not fit into the risk assessment scenario or economists' cost/benefit techniques. Every day we obliterate thousands of acres of our natural landscape and the biological entities that inhabit these areas. Except for commercial grade lumber and some game species, we assign little or no value to the existence of the natural environment and the plants and animals that exist there. Long-term effects of continued loss of habitat can be profound. We know that we will have many more people 100 years from now. Even if we reduce our individual impacts on the environment and reduce per capita use of our natural resources, our cumulative impact will result in ever increasing demands and conflicts between the needs of human beings

and the biosphere. We know we have undervalued some of what we have lost forever. We shouldn't make the same mistakes again through greed and insensitivity. Risk assessments should not be inappropriately used to undervalue natural systems. Because there may be a low or insignificant risk to humans, unquantifiable risks to plants and animals or unquantifiable risks associated with loss of habitat must not be ignored, and should be considered on the merits. We need better tools to protect high value natural areas.

High risks can be usually be lowered by reasonable efforts. Zero risk cannot always be achieved at any cost. Some of the worst environmental "sins" are the result of avoiding or deferring legislation that would lower risks through reasonable efforts -- i.e., deferral of the Clean Air Act in the 1980's. Some of the worst case scenarios are created by laws and regulations that are overreaching towards zero risk that cannot be achieved. In between it is our challenge to decide what risks are acceptable and what risks can be reduced or eliminated. Good information as required by the risk assessment title you are considering and will help us make these decisions.

Thank you for this opportunity to testify.

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# Kentucky Outlook 2000:

*A Strategy for Kentucky's Third Century*



A KENTUCKY OUTLOOK 2000

*The Kentucky Natural Resources and Environmental Protection Cabinet  
The Kentucky Long-Term Policy Research Center*

1994



# Kentucky Outlook 2000... *A Strat*

## Project Overview

*Reducing Risks Today, Tomorrow*

Kentuckians need a clear vision of the Commonwealth's present condition and preferred future if we are to achieve our mutual goals of a healthy environment and a sustainable, thriving economy. This vision can only be prepared with the help of Kentuckians from all walks of life — government, businesses, advocacy organizations and the general public.

*Kentucky Outlook 2000: A Strategy for Kentucky's Third Century* is an exciting new project crafted to focus our efforts toward achieving these interdependent goals. The project has two parts: the "Futures" element and the "Comparative Risk" initiative.

### Futures

The "Futures" element is a process to help determine what citizens of the Commonwealth want for our future. Project participants will develop strategies to address challenges Kentucky faces in achieving our shared vision. This component is directed by the state's new Long-Term Policy Research Center.

### Comparative Risk

"Comparative Risk" is a process to identify and evaluate risks posed by environmental problems such as water pollution and resource depletion. Project participants will identify and rank the problems based on their risk to human health, ecological systems and our quality of life.

This ranking will be useful in determining which risks pose the greatest threats to people, the environment, and economic vitality. The "Comparative Risk" initiative will help Kentucky target its resources to address the most serious problems and shape strategies for reducing those risks.

The Natural Resources and Environmental Protection Cabinet, in conjunction with the Long-Term Policy Research Center, has been awarded a grant by the U.S. Environmental Protection Agency to implement this unique partnership.

The process of combining futures planning with environmental priority setting is the first of its kind in the United States.

## The Purpose

*A Shared, Measured Vision*

More than just a basic ranking of Kentucky's environmental risks, the purpose of this public and private partnership is to determine the dimensions of many critical economic, social, and technological issues facing the Commonwealth.

The project offers an opportunity for Kentuckians to participate in shaping a "shared vision" of natural resource management that will serve our present and future needs.

This project should help launch progressive public policies that carry our vision into Kentucky's third century.

### Project Goals

- Measuring and ranking Kentucky's environmental problems and their associated risks using "Comparative Risk" techniques
- Developing strategies to reduce risks to health, the environment, and quality of life.
- Improving environmental protection and natural resource management in Kentucky.
- Creating a shared vision of Kentucky's environmental priorities and determining our "preferred" future.
- Measuring progress toward achieving our shared vision, in cooperation with the Long-Term Policy Research Center.



## The Strategy—

*Comparative Risk*

The Comparative Risk, or environmental prioritizing, part of the project has four phases:

- Phase I... *Project Planning*
- Phase II... *Issues Analysis, Risk Ranking*
- Phase III... *Risk Management Strategies*
- Phase IV... *Action to Reduce Risks*

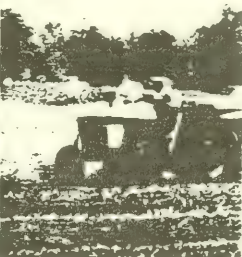
**Management** —The Steering Committee, composed of representatives from all regions in Kentucky, will manage oversight policy decisions about the project.

**Analysis** —The foundation of the project is an analysis of the risks associated with each risk that will be addressed. A Technical Committee and its subcommittees, comprised of Kentucky's most prestigious scientists, economists, and leaders in other fields of expertise, will analyze risks associated with three major impact areas:

- Ecological Systems
- Human Health
- Quality of Life

**Outreach** —This is a public project.

A "Public Advisory Committee," coordinate the Kentucky Environmental Quality Commission, along with the technical teams, will rank risks and devise strategies for effective problem solving.





## for Kentucky's Third Century

### The Strategy— Futures Planning

The Long-Term Policy Research Center has begun the Futures element by soliciting "position papers" from 300 experts in all fields of interest. Contributors were asked to analyze an issue area with regard to its historical context, current status, and likely future trends affecting the Commonwealth.

The information will be used to develop possible "future scenarios" that identify expected outcomes associated with our public policies. These scenarios will be presented during 15 public forums scheduled for the project's second year.

Focus groups comprised of representatives from universities, business, agriculture, state government, and other interest groups will explore the issues and consider future actions necessary to maintain a sustainable, high quality of life.

The focus groups and those who attend the forums will identify a "preferred future" for the Commonwealth, and strategies necessary to achieve the highest possible quality of life for all Kentuckians.

The Long-Term Policy Research Center will ask communities to identify goals, objectives and strategies to achieve the desired future. The Center will hold a statewide conference to offer Kentuckians a voice in the project.

### Results A Sustainable Future

The project results will include

- Improved environmental management
- Risk-based environmental priorities
- Scientific basis for decision-making
- Action plans to reduce risk
- Coordination between agencies/groups
- Measurable, defined strategy for the future

#### ■ Issues Reports

The Project Work Group will produce reports for each issue area after collecting data. These will include information about the risks to human health, ecological systems, and quality of life, including future scenarios.

The Work Group will make reports accessible to the public. Project Committees, using the reports, will evaluate data and rank the issues relative to risk. The Public Advisory Committee will recommend risk reduction strategies based on ranking.

#### ■ Project Report

The Project Committees will issue a report summarizing the project. This report will be used as a basis for Environmental Management Plans that focus on reducing risks and solving environmental problems.

#### ■ Management Plans

The Project Committees will develop management plans to improve the method by which state government allocates resources.

### Your Involvement The Key to Success

You can serve an important role by attending public meetings and providing input into the project's many public outreach elements.

The Public Advisory Committee, in partnership with the Natural Resources and Environmental Protection Cabinet's Public Information/Education Workgroup, is responsible for an outreach program that encourages your involvement. The committee and Work Group will provide information about the project through newsletters, regional meetings and other opportunities. The eight teams working on public outreach are:

- Education
- Media
- Regulated Community
- Regional Field Offices
- Local Government
- Conservation Districts
- EQC Forums

Members of these committees, and the futures focus groups, represent all major interest groups and geographical regions of the state. You can offer a valuable service to the committees by providing input to members about issues you consider important.

You can stay informed about the work of the Steering Committee, the Technical Committee and the Public Advisory Committee and their scheduled activities through a monthly newsletter. The Futures component also offers information to the public.

To receive the newsletter or more information about the Comparative Risk Project, contact  
Comparative Risk Coordinator  
14 Reilly Road  
Frankfort, Kentucky 40601  
(502)564-2150

To receive information about the Futures Project, contact  
Long-Term Policy Research Center  
(502)564-2851



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## Comparative Risk Steering Committee

(As of March 1, 1994)



*The Honorable Mark Brown, Kentucky House of Representatives\**  
*Michael Childress, Director, Long-Term Policy Research Center*  
*The Honorable Herbie Deskins, Kentucky House of Representatives\**  
*Dr. Larry Elliot, President, Kentucky Academy of Science*  
*Tom FitzGerald, Director, Kentucky Resources Council*  
*Gordon Garner, Executive Director, Louisville Metropolitan Sewer District*  
*Peggy Jackson, Executive Secretary, Kentucky Association for Community Action*  
*Don Kelly, Secretary, Transportation Cabinet*  
*Elizabeth Lloyd Jones*  
*Cary Larimore, Executive Director, Kentucky Rural Water Association*  
*Crit Luallen, Secretary, Tourism Cabinet*  
*Robert Logan, Commissioner, Department for Environmental Protection*  
*Dr. William Martin, Commissioner, Department for Natural Resources*  
*Mike Holm, Superintendent, Mammoth Cave National Park*  
*Mary Helen Miller, Chief of Staff, Governor's Office*  
*Mike Musulin, Chairman, Alliance of Kentucky Coal Associations*  
*Janet Myer, Kentucky Association of Counties*  
*The Honorable Kim Nelson, Kentucky State Senate*  
*Tom Nessmith, Region IV, U.S. EPA*  
*John Nichols, Vice President, Associated Industries of Kentucky*  
*Brad Powell, Supervisor, Daniel Boone National Forest*  
*The Honorable Rick Rand, Kentucky State Senate\**  
*Tony Sholar, Kentucky Chamber of Commerce*  
*The Honorable Ernesto Scorsone, Kentucky House of Representatives*  
*Phillip Shepherd, Secretary, Natural Resources and Environmental Protection Cabinet*  
*Dr. Mary Smith, President, Kentucky State University*  
*Mayor Paul Smith, Kentucky League of Cities*  
*William Sprague, President, Kentucky Farm Bureau Federation*  
*Marvin Strong, Secretary, Economic Development Cabinet*  
*Dr. Lee Todd, Kentucky Science and Technology Council*  
*Barry Tonning, President, Kentucky Conservation Committee*  
*Ray Tucker Jr., Chairman, Kentuckians For The Commonwealth*  
*Dr. Welby Winstead, University of Louisville*

\*invited

### Natural Resources and Environmental Protection Cabinet

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*Karen Armstrong-Cummings, Deputy Secretary*

*Nancy Fouser, Project Manager (502)564-2150*

*Erik Siegel, Project Coordinator (502)564-2150*

### Public Advisory Committee

*Environmental Quality Commission*

(502)564-2150

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*Gordon Garner, EQC Vice Chair*

*Leslie Cole, Executive Director*

### Comparative Risk Work Group

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*Connie Ashcraft*

*Russ Barnett*

*Malena Chamberlain*

*Leslie Cole*

*Joe Dietz*

*Richard Green*

*Pat Haight*

*Kay Harker*

*Stanley Head*

*Robert McCance*

*Dr. David Morganti*

*Vicki Pettus*

*Richard Rohlf*

*Ruth Rowles*

*Julie Smither*

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*Representative Ernesto Scorsone, Vice Chair*

*Michael Childress, Executive Director*

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*William Hintze, Jr.*

*Edward Holmes*

*Mary Helen Miller*

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*Sen. Nick Kafoglis*

*Sen. Joe Meyer*

*Rep. Steve Nunn*

*Rep. John Will Stacy*

### At-Large Members

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*Paul Cook*

*Janie Douglass*

*Betty Griffin*

*Vic Hellard, Jr.*

*Ric Ledt*

*Robert McCowan*

*Penry Miller*

*Joan Richm*

*Robert Sexton*

The CHAIRMAN. Thank you, Mr. Garner.

Next we will hear from Mr. Sam Kazman, who is the general counsel of the Competitive Enterprise Institute.

Mr. Kazman.

Mr. KAZMAN. Thank you, Mr. Chairman, for the opportunity to testify today.

Title III attempts to make agencies do a better job of thinking. The need for improvement here is clear. As Supreme Court Justice Stephen Breyer demonstrates in his short, elegantly short, book, "Breaking The Vicious Circle," today we have agencies spending hundreds of millions of dollars to eliminate products that are less risky than something we all usually carry around in our pockets, products that are less risky than toothpicks. He was referring to EPA's attempt to ban asbestos-containing piping and shingles, an attempt that was overturned in the Federal court case. The court found that EPA was prepared to spend hundreds of millions of dollars to save a product that is less risky than a toothpick.

Now toothpicks, I remind you, can be dangerous. In fact, about one person a year dies from accidentally ingesting a toothpick. Some people, some agencies, would call this a killer toothpick [indicating toothpick], and I suspect that if this device was not a centuries-old product that we all know but had come out of a laboratory last year, I would have needed a permit to carry it, I would need to be wearing a moon suit, and I would have to have cleared out this entire courtroom before I could reveal it—this committee room.

Professor Graham alluded to a decision involving the National Highway Traffic Safety Administration, a case entitled Competitive Enterprise Institute v. NHTSA. In that case, the court found that an agency whose middle name is safety was running a program that killed people and, worse yet, was doing its best to conceal it. In the court's own language, NHTSA was using a combination of "statistical sleight of hand", "fudged analysis", and "bureaucratic mumbo-jumbo" to avoid dealing with the fact that its CAFE program in all likelihood kills people.

But before we can improve how agencies think, we have to look at why they are thinking the way they do. H.R. 9 sets out a number of very technical sounding factors that agencies are directed to consider. Now those factors sound technical, but really they can be very simply described in layman's language. Agencies should ask: Do we really need this rule? Will it work? What will it cost? What is the likelihood that it won't work? What happens if it fails? Could we get by—what could we get instead with the money we would be spending on this?

Those are things that people and companies in the private world consider all the time, and so at first blush it seems incredible that agencies are not considering them. But that is only at first blush, because if you examine how agencies operate you find that in certain ways they are very different from people and entities in the private world.

To begin with, they are not spending their money, they are spending ours; secondly, when they make mistakes, they don't directly pay for the consequences of those mistakes; and third and

most important, what that means is, they don't learn from their mistakes the way you and I do in the private world.

Agencies are different from us, but in certain other ways they are very similar to us: They have desires, they want to expand their jurisdiction, they love to expand their budget, they have difficulty dealing with conflicts. These forces are things that some analysts call institutional incentives, and one important thing in regulatory reform is to recognize what institutional incentives are when it comes to agencies and make sure that we take advantage of them, of those incentives, and not that those incentives take advantage of us, and that, for example, is one reason that we would strongly recommend that the peer review instituted under subtitle III not be a responsibility placed with individual agencies, because we suspect pretty quickly agencies will learn how to bend that to their advantage. Instead, find an overriding agency—an oversight agency whose job it is to rein in agencies; let it take responsibility for peer review on a Government-wide basis, and the Office of Management and Budget, we submit, is one place to certainly look.

Secondly, this committee should seriously consider imposing an across-the-board requirement that the benefits of any rule be shown to exceed its costs. Now some people might think, wait, that means we are, by implication, amending a vast number of laws, but I submit to you that as an operating principle for government it is not a bad starting point that any rule's benefits exceed its risks and costs. In that situation that rule, we submit, should be made the rule, not the exception.

If, in fact, there are cases where exceptional circumstances demand an exception, Congress can certainly come back to those exceptions and deal with them on a case-by-case basis, but as a general operating rule it is a good point to start with the very fundamental notion that rules should be producing benefits for us.

Our third proposal is that we put an end to what we can call regulation by hypothecation. We have hypothetical threat after hypothetical threat being presented as the rationale for agency action, the threat of a killer toothpick. Some of the worst cases of regulatory abuse have occurred in those areas. For example, EPA's campaign on residential radon is based almost solely on extrapolations from the incredibly high concentrations of radon found in uranium mines. They take those levels, they extrapolate down to the levels found in our houses, and they say whoa, there is a threat. Yet in fact the best work on this issue, something that appeared in the December issue of the *Journal of the National Cancer Institute*, a study of over 500 nonsmoking lung cancer cases, could find no causative factor for residential radon. Residential radon, in its view, is simply not a detectable risk factor.

We submit that if a proposed rule, a health and safety rule, by an agency, is not based on direct or epidemiological evidence involving humans at the exposure levels that are at issue—you are talking about homes—talk about home levels, not miners' levels; if it is not based on that sort of evidence, then it should not receive the deference that courts usually give to agency action. Instead, let that rule be based on a preponderance of the evidence.

Some people might think, well, doesn't that make us all guinea pigs, and the answer is no. I submit to you that we are already

guinea pigs. When we have a regulatory system that causes school systems to be shut down because of fears of asbestos for months on end, we are already guinea pigs. When we have a regulatory system that shuts down the town of Times Beach, Missouri, only eight years later to have the Government scientists come back and say, "Well, in retrospect maybe that was a mistake, but at least we erred on the side of human safety," that also makes us guinea pigs. To shut down a town, to destroy or disrupt the lives of 2,000 people, to create at least one suicide, to make these people think that they are walking carcinogenic timebombs, that is not erring on the side of human safety.

Remember, if you are in a crowded theater, you don't yell "Fire!" at the first whiff of something, you want to make sure it is smoke, and there is a good reason for that, because if you yell "Fire!" and you have a mass panic and people get hurt evacuating, you don't later say, "Gee, that was a mistake, but better safe than sorry." That isn't playing it safe, but in fact we have agencies doing the equivalent of that all the time, yelling toxic terror, carcinogen, hazardous waste.

H.R. 9 is a very good attempt to begin forcing agencies to think before they shout and to take responsibility for what happens after they shout "Fire!" in a crowded theater, and it will remove us from the status of being guinea pigs and allow us to get on with our own lives.

Thank you.

[The prepared statement of Mr. Kazman follows:]



COMPETITIVE ENTERPRISE INSTITUTE

TESTIMONY OF SAM KAZMAN, COMPETITIVE ENTERPRISE INSTITUTE,  
BEFORE THE COMMITTEE ON SCIENCE OF THE  
U.S. HOUSE OF REPRESENTATIVES ON TITLE III OF H.R. 9,  
"RISK ASSESSMENT AND COST/BENEFIT ANALYSIS FOR NEW REGULATIONS

On behalf of the Competitive Enterprise Institute, I wish to thank this Committee for the opportunity to testify here today. CEI is a nonprofit organization dedicated to advancing private solutions to regulatory issues. CEI has long had a special interest in raising public awareness of the hidden costs, human as well as monetary, of overregulation. One major CEI effort, our "Death By Regulation" project, focuses on regulations which are not only costly in financial terms, but which also are, quite literally, lethal.

The need for regulatory reform is illustrated by one striking example of "Death By Regulation"--the federal government's new car fuel economy standards, popularly known as the CAFE rules (for Corporate Average Fuel Economy). The CAFE program is administered by the National Highway Traffic Safety Administration. NHTSA has long known that one of CAFE's major effects is the downsizing of new car models; it has also known that, in general, smaller cars are less crashworthy than large ones. Nonetheless, for over a decade NHTSA has steadfastly insisted that CAFE has no lethal effect fact on traffic safety.

In 1992, as a result of litigation brought by CEI, the illogic, and illegality, of NHTSA's position was recognized by a

federal appeals court. Ruling in the case of CEI v. NHTSA, the court found that NHTSA's attempt to whitewash CAFE was based on "fudged analysis", "statistical legerdemain", and "bureaucratic mumbo-jumbo". 956 F.2d 321, 323, 327 (D.C. Cir. 1992).

NHTSA has not changed its position on CAFE in the wake of this decision, and so we are once again back in court.

CAFE is but one example of regulatory insanity. There are countless others. One question that must be asked of any regulatory reform measure is whether it would have prevented such instances. The answers are not always clear, but there is no questioning the need for reform in this area.

If enacted, Title III of H.R. 9 would constitute a major advance on this issue, directing agencies to carefully consider a host of factors that are often neglected in government contexts. With respect to any proposed rule, these factors can easily be described in layman's language: Do we really need this? Will it work? Is it worth the cost? What could we get instead with the money we're about to spend on this?

These are factors that individuals and private organizations routinely consider on a daily basis, and so at first blush their absence from agency decisionmaking is remarkable. But in fact there are some fundamental reasons that explain this. When agencies regulate, it is not their money or their lives that are on the line. When they make mistakes, they do not pay for them in the same way that you and I pay for our mistakes.

Differences such as these between agencies and private parties explain some of the unique features of government decisionmaking. But there is another element as well, involving not differences, but similarities between agencies and people. Like people, agencies have desires--they want to expand their jurisdiction, their budgets, and their power. Like people, agencies have difficulty dealing with conflicts. Like people, agencies do not like to be embarrassed.

These institutional incentives should be officially recognized by Congress in section 3001 of H.R. 9.<sup>1</sup> This is not an insignificant rhetorical issue. The idea that agencies sometimes pursue their own interests, at the expense of the public interest, is supported by a vast body of research; it is also supported by our experience with overregulation, which is why the issue of regulatory reform is so high a priority in this Congress. Nonetheless, this idea is still often regarded in government circles as the harping of disgruntled critics. Congressional recognition of this concept would not only add to its stature; it would also enable courts and other entities to readily utilize it in analyzing agency action.

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<sup>1</sup>. See, for example, Title VI, Sec. 601, of H.R. 5229 (102d Cong., 2d Sess.): "The Congress finds that--(1) administrative action is too frequently propelled by a concern with politically visible results, at the expense of less apparent impacts; ... (3) in promulgating regulations, agencies often fail to examine the risk that their suppositions are erroneous, or to compare the risks of acting on faulty suppositions with the risks of inaction ...."

The existence of such institutional incentives means that we cannot reform agencies by simply "reprogramming" their decisionmaking with such additional factors as substitution costs. We cannot simply direct them to do a better job and leave it at that. We must also change those incentives, and we must find other institutions, such as courts and oversight agencies, whose institutional focus is on reviewing and restraining regulatory action. For this reason, it is extremely important that Title III's judicial review provision, section 3301(e), be retained. In fact, that provision should be expanded, to ensure that all cost-benefit and risk assessment materials are available to the courts in cases challenging agency action. This is the single best guarantee that the improved analyses mandated by H.R. 9 will lead to improved administrative decisionmaking.

Recognition of institutional incentives also suggests that the peer review mandated under Subchapter 3 should not be placed in the hands of the agencies themselves, as it is in the current version of H.R. 9. Agencies will inevitably tend to skew the peer review process in their favor. Peer review should instead be the responsibility of an entity whose institutional responsibility is to review and restrain agency action. The Office of Management and Budget is one such entity, and it is perfectly situated to institute peer review mechanisms on a government-wide basis. For this reason, peer review should be OMB's responsibility, rather than that of individual agencies.

H.R. 9 expressly disclaims any intent to modify "any statutory standard or requirement designed to protect health, safety, or the environment." Sec. 3013(c). We submit that, in fact, H.R. 9 should do the opposite--it should modify these and other statutes to require that every regulatory action be shown to produce a net benefit.<sup>2</sup> This is, in a sense, an unarguable governing principle. If there are proper exceptions to it, then Congress can institute them on a case-by-case basis; what is important is that they be exceptions, rather than the rule.

NHTSA's administration of CAFE is one such example. While the court decision in CEI v. NHTSA helped bring NHTSA's misconduct to light, the agency itself has not altered its position in the wake of this case. More importantly, the case itself might have had a totally different outcome if NHTSA had adopted a different construction of the underlying CAFE statute--one that did not encompass safety as one of the decisional criteria.<sup>3</sup> A substantive requirement that NHTSA minimize the

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<sup>2</sup>. Assessing the often unrecognized costs of regulatory waiting periods is an essential part of this process. This Committee should consider requiring any agency that acts as a "gatekeeper" for new products to undertake a "Post-Approval Audit"--that is, an assessment of what society lost while waiting for a new product to be approved. Regulatory delays impose a toll in terms of foregone benefits--in the case of a life-saving drug, for example, people clearly may die while the drug application is being considered. This regulatory cost usually is swept under the rug.

Such audits are described and recommended in NIH, 1992 National Biotechnology Policy Board Report at 4, E29-30.

<sup>3</sup>. As the CEI v. NHTSA decision expressly notes, such a statutory construction "would have had a fair shot at being upheld." 956 F.2d at 323.

harm of its regulations would have reduced the likelihood of NHTSA embarking on the course that it chose.

This Committee should also recognize that "health, safety and the environment" have been the occasion for some of the worst cases of unfounded regulation. For example, in terms of cost to save one "statistical" life, EPA's regulations are the most expensive imposed by the federal government.<sup>4</sup> One frequent approach in such areas has been for agencies to extrapolate from extremely high concentrations of some toxin, and then claim that by reducing the low concentrations of this agent in everyday life, we could save some number of lives.

Such claims are couched in scientific terms, but in fact they are not scientific at all. As two experts in this field have noted, the product of a risk assessment is a hypothesis--it is a prediction of what will happen in the world. The problem, however, is that the predicted risks from most such assessments are so small that there is no possible way to detect these allegedly life-saving effects.<sup>5</sup> For example, a one in a million increased lifetime risk of cancer, a level which EPA often cites as its level of concern, translates to three cancers a year. This risk level, however, is simply undetectable in the American

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<sup>4</sup>. Tengs, T.O., M. Adams, J.S. Pliskin et al (1994), "Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness", Risk Analysis (in press).

<sup>5</sup>. Gough, M. and J. Wilson (1994), "Understanding the Relationship Between Science and Risk Analysis", AIHC Journal 2 (1):12-15 (based on a paper presented at the Annual Meeting of the Society for Risk Analysis in 1993).

population, given that there are over 500,000 deaths from cancer per year in this country.

In short, such regulatory claims may sound like science, but they are not scientific. The essence of scientific hypotheses is that they are testable, and these regulatory claims simply are not testable.

Given the history of regulatory abuse in this area, this Committee should consider raising the threshold of proof required by agencies in these cases. One approach would be to mandate that, unless an agency has direct or epidemiological human evidence concerning a chemical at or below the exposure level at issue, then any regulation based on the human risk of this substance shall not be entitled to a presumption of validity. It would instead have to be supported by a preponderance of the evidence.

This would still allow an agency to act in the face of strong indirect evidence, but it would reduce the sort of hypothetical and untestable risk regulation that has increasingly proven to be groundless in recent years.<sup>6</sup>

As one very cogent analysis (attached) demonstrates, much current risk regulation resembles the witch hunts of centuries

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<sup>6</sup>. For example, EPA's alarums regarding residential radon are based on extrapolations from uranium mines. In contrast, the most extensive study to date of residential radon exposure, a study of over 500 nonsmoking lung cancer cases, found no risk from radon at the levels commonly present in homes. Alavanja, Brownson, Lubin et al., "Residential Radon Exposure and Lung Cancer Among Nonsmoking Women", J. National Cancer Institute 86:1829-37 (1994).

past. During the Inquisition, people suspected of witchcraft were subjected to one form of questioning; if they didn't confess, then they were subjected to another ordeal, and then another, until they did confess. Today we torture data instead of people; if one type of analysis fails to show carcinogenicity, then we try another and another until we finally find the "proof" we're after.

H.R. 9 represents a significant step forward in putting an end to this madness. The proposals that we have submitted would make this even more effective. Most important, however, is recognizing this insanity in the first place. Regulation in this country has gone seriously wrong, and hearings such as this can perform no greater service than raising public recognition of this fact.

Respectfully submitted,  
Sam Kazman, General Counsel,  
Competitive Enterprise Institute

January 30, 1995

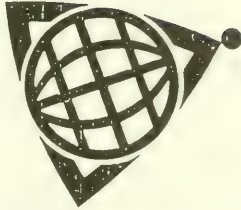
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# WITCHES, FLOODS, AND WONDER DRUGS: HISTORICAL PERSPECTIVES ON RISK MANAGEMENT

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## ABSTRACT

Risk is a people problem, and people have been contending with it for a very long time indeed. I extract some lessons from this historical record and explore their implications for current and future practice of risk management.

Socially relevant risk is not uncertainty of outcome, or violence of event, or toxicity of substance, or anything of the sort. Rather, it is a perceived inability to cope satisfactorily with the world around us. Improving our ability to cope is essentially a management problem: a problem of identifying and carrying out the actions which will change the rules of the game so that the game becomes more to our liking.

To cope better is to better understand the nature of risks and how they develop, to better understand the nature of our own actions, and to better understand the uncertainties and complexities of traditional science. Risk management lies in the realm of trans-science, of ill-structured problems, of messes. In analyzing risk messes, the central need is to evaluate, order, and structure inevitably incomplete and conflicting knowledge so that the management acts can be chosen with the best possible understanding of current knowledge, its limitations, and its implications. This requires an understanding in policy analysis, rather than science.

One product of such analyses is a better conceptualization of "feasibility" in risk management. Past and present efforts have too often been both frustrating and wasteful.

Another is an emphasis on the design of resilient or "soft-fail" coping strategies. The essential issue is not optimality or efficiency, but robust-

ness to the unknowns on which actual coping performance is contingent. The most important lesson of both experience and analysis is that societies' abilities to cope with the unknown depend on the flexibility of their institutions and individuals, and on their capability to experiment freely with alternative forms of adaptation to the risks which threaten them.

Neither the witch hunting hysteria nor the mindlessly rigid regulations characterizing so much of our present chapter in the history of risk management say much for our ability to learn from the past.

### FEAR, RISK, AND HISTORICAL PERSPECTIVE

At the center of the risk problem are people and their fears. Fears of loss, fears of injury, and — most of all — fears of the unknown. How we cope with those fears affects both the material well-being, and the spiritual character of the individuals and societies we become.

Students of risk therefore face a number of difficulties in addressing their subject matter, and surely one of the most serious is that of establishing a useful perspective. The fears of risk are our fears, the people making and taking risks are ourselves and our neighbors. When we intellectualize ourselves away from these ambiguities, our work becomes sterile, our subjects ciphers. When we tackle them directly, our involvement makes critical interpretation impossible and broader interpretations irrelevant. Unable to see inside the problem, we trivialize it. Unable to see outside the problem, we become part of it.

I suspect that work on contemporary risks will always contain some elements of this contradiction. To better appreciate the problem we are in, to better orient our directions for the future, a backward look into the history of societal risk assessment therefore seems in order. With the perspective of time, we should be able to perceive some of the pitfalls and opportunities of risk management which our intimate involvement in the contemporary scene denies us.

Unfortunately, what must have been a truly monumental environmental impact assessment on the Seven Days of Creation has been lost. But societal risk assessment nonetheless has a history as long as man's efforts to explain, manipulate and cope with his fears and the unknown. Much of this is still accessible to us, and should have some lessons to teach. That at least is a possibility, and one that has not yet been explored.

For several years now I have been trying to convince some competent historians to undertake a retrospective study of societal risk, all to no avail. The present historical "essay" is the result, and I emphasize that I use the term in its original sense of an amateur's first attempt. That attempt has been fun, and has provided me some interesting perspectives on our present risk dilemmas. I hope its transgressions of historical fact will sufficiently outrage professionals that their rebuttals can begin the serious study which I seriously do believe is needed.

In the next three sections I review what seem to me three particularly instructive episodes in the history of societal risk assessment. The European witch craze of the 16th and 17th centuries is treated in the first section, some North American

experience in renewable resource management in the second section, and medical drug regulation in the third. The historical perspective derived from these three studies is then used to shed some light on the unasked question of "What are we arguing about?" in the contemporary risk debate. Finally, I look forward to the prospects for adaptive design of risk management policy.

### WITCH HUNTS: ON THE SOCIAL PSYCHOLOGY OF RISK\*

For several centuries spanning the Renaissance and Reformation, societal risk assessment meant witch hunting. Contemporary accounts record wheat inexplicably rotting in the fields, sheep dying of unknown causes, vineyards smitten with unseasonable frosts, human disease and impotence on the rise. In other words, a litany of life's sorrows not very different from those which concern us today. The institutionalized expertise of that earlier time resided with the Church. Then, as now, the experts were called upon to provide explanation of the unknown and to mitigate its undesirable consequences. Rather than seek particular sources of particular evils, rather than acknowledge their own limitations and ignorance, these experts assigned the generic name of "witchcraft" to the phenomenon of the unknown. Having a name, they proceeded to found a new professional interest dedicated to its investigation and control.

As the true magnitude of the witch problem became more apparent, the Church enlisted the Inquisition, an applied institution specifically designed to address pressing social concerns. The Inquisition became the growth industry of the day, offering exciting work, rapid advancement, and wide recognition to its professional and technical workers. Its creative and energetic efforts to create a witch-free world unearthed dangers in the most unlikely places, the rates of witch identification, assessment and evaluation soared. By the dawn of the Enlightenment, witches had been virtually eliminated from Europe and North America. Crop failures, disease, and general misfortune had not. And more than half a million people had been burned at the stake, largely "for crimes they committed in someone else's dreams" [2, p. 221].

How did the expert institutions of the day come to wreak such havoc on the people they sought to protect? Answers to this question provide some useful perspectives for our present attempt to assess societal risk.

Witches and witchcraft can be traced back to the very beginnings of history. For centuries, people had found "witches" a convenient label for their fears of the unknown, an adequate explanation for the inevitable misfortunes which befell one's crops, health, and happiness. For centuries, the Church adopted a skeptical and largely academic approach to these explanations, preaching the difference between fact and fantasy, and placing witches squarely in the latter category. Witchcraft, if it existed at all, was an illusion sent by the devil. These illusions were

\*This essay draws from *Troyan Roper III, Heretic III, Devil's transience of the Melrose* [4].

frowned upon and even prohibited by law. But individual witches and witch mongers were not sought out by the Church and, if brought to its attention, were merely advised of their errors and urged to desist. Persistent individuals were simply excommunicated. The social structure, represented by the Church, declared itself no longer interested in or responsible for the welfare of those individuals. If the miscreants chose to ignore responsible advice, their subsequent fate was their own business, and the devil's. Witches remained an individualized risk, requiring individual responses by individual members of the Church and by communities.

Wildavsky [5] has spoken of the "watershed" which is passed when such individualized issues are collectivized under unified social policies. Instigator and Springer's *Malice Maleficarum* (*The Hammer of the Witcher*, published in 1486) was for the witch hunting business that collective consciousness watershed which Kefauver's *Hearings* would later be for drug regulators, and Rachel Carson's *Silent Spring* for environmentalists. Massive in its scope and evidence, impelling in its argument, the *Malice* showed that witches did in fact exist, with real power for evil. As agents of Satan, they were a heresy — a dangerous sin in need of eradication. Not individuals, but society as a whole was in peril as long as witches remained at large. Pope Innocent VIII credited this argument, and his bull *Summi desiderantes affectibus* authorized full application of the Inquisition, including torture, to the eradication of witches. The witch risk, to use another of Wildavsky's [5] terms, had been "socialized." Collective action by the central authority was henceforth required, and any action taken against a particular individual was justified in the name of the common good. In the case of the witch hunts, this "common good" justified the carbonization of five hundred thousand individuals, the infliction of untold suffering, and the generation of a climate of fear and distrust — all in the name of the most elite and educated institution of the day.

Modern risk assessors do not incinerate their fellow citizens. Furthermore, they seek to insure against milder forms of witch hunting by a scientific approach to gathering and evaluating evidence on risk issues. But the history of witch hunting suggests that what we say we are doing or wish to be doing in contemporary risk assessment may be far removed from what actually occurs. Again, the historical perspective may help us to recognize some of these discrepancies, and to provide a basis for their rectification.

The institutionalized efforts of the Church to control witches can be seen, in retrospect, to have led to witch proliferation. Early preaching against witchcraft and its evils almost certainly put the idea of witches into many a head which never would have imagined such things if left to its own devices. The harder the Inquisition looked, the bigger its staff, the stronger its motivation, the more witches it discovered. Similar trends have been documented in the modern literature on hazard and have long posed difficulties for those seeking to document the crime prevention effectiveness of larger policy forces [e.g., Fig. 1-1]. A general question therefore arises concerning the causal relationship between assessment and risk. Which is driving which? A strong case can be made for the notion that search effort creates the thing being sought. Since the resulting higher discovery rate of witch risks obviously justifies more search effort, the whole process becomes self-

contained and self-amplifying, with no prospect of natural limitation based on some externally determined "objective" frequency of witch risks in the environment.

The way we ask questions, and the kinds of evidence we admit in our attempts to answer them, are of the utmost importance here. The Inquisition asked "Are you a witch?" and proceeded to examine the evidence to see if you were. Today, whatever we title our symposia, we ask "Is this a risk?" and proceed accordingly. In neither case is there any conceivable empirical observation rule which could logically force an answer "No." In neither case is there a "stopping rule" which can logically terminate the investigation short of a revelation of guilt.

In witch hunting, accusation was tantamount to conviction. Acquittal was arbitrary, dependent on the flagging zeal of the prosecutor. It was always reversible; if new evidence appeared, you couldn't win, and you could only leave the game by losing. The Inquisition's principal tool for identifying witches was torture. The accused was asked if she was a witch. If she said no, what else would you expect of a witch? So she was tortured until she confessed the truth. The inquisitors justified ever more stringent tortures on the grounds that it would be prohibitively dangerous for a real witch to escape detection. Of course an innocent person would never confess to being a witch (a heretic with no prospects of salvation) under more physical suffering. The few who lived through such tests were likely to spend the rest of their lives as physical or mental cripples. Most found it easier to give up and burn.

And now? What is not a risk with a parts-per-trillion test can always be exposed to a parts-per-billion examination. If rats cope with the heaviest dose of a chemical that can be soaked into their food and water, you can always gagage them. Or try mice or rabbits. Again, the only stopping rule is discovery of the sought-for effect, or exhaustion of the investigator (or his funds). Many of the risk assessment procedures used today are logically indistinguishable from those used by the Inquisition. The absence of "stopping rules" means that both fail to meet Popper's [7] "demarcation" criterion for true science. Since neither is advancing falsifiable propositions, neither is capable of producing anything more than propaganda in support of its own prejudices.

Modern science's defense against self-delusion relies upon a spirit of open and critical inquiry. This, though hardly infallible, ostensibly uncovers errors and thereby proceeds towards objective truth. Once again, however, exactly the same high principle failed in actual practice during the heyday of the Inquisition. Within the 16th century Church, hardly a voice was raised against the witch hunt, while those outside defended the accused only at great personal risk. After all, argued the *Malice*, with such crop losses, child mortality, marital infidelity, and general aches and pains as exist today, "Who is so dense as to maintain . . . that all their witchcraft and injuries are phantasmic and imaginary, when the contrary is evident to the senses of everybody?" Who, indeed? Only those in league with the devil.

"On 'propaganda' in this context, see Feyerabend [8]. It is worth noting that both witch hunts and risk assessments also fail to meet Kuhn's weaker 'puzzle solving' criterion of science [9]."

And so the few philosophers and physicians who did speak up against the hunts were themselves harassed, excommunicated, and in many instances burned along with the witches.

Today, anyone querying the zeal of the risk assessors is accused at least of callousness, in words almost identical to those used by the *Mallevs* five hundred years ago. The accused's league with the devil against society is taken for granted. Persecution in the press, courts, and hearing rooms is unremitting, and even the weak rules of evidence advanced by the "science" of risk assessment are swept away in the heat of the chase (see section on medical drug regulation below). This is not to say that risks don't exist, or that assessors are venal. It is to insist that skeptical, open inquiry remains theory rather than practice in the majority of today's risk debates. That those debates are so often little more than self-deluding recitations of personal faith should not be surprising.

A last insight into our modern treatment of risk evidence comes from the historical demise of witch hunting as a profession. In 1610, after a century of witch hunting, the exceptional Inquisitor Alonso Salazar y Frías carried out an extensive analysis of witch burnings at Legorono, Navarre. He showed that most of the original accusations had been false, that torture had created witches where none existed, and that there was not a single case of actual witchcraft to show for all the preaching, hunting, and burning which had been carried out in the name of the Church. He did not rule on whether witches existed. He did order that the Spanish Inquisition no longer use torture under any circumstances, and that accusations no longer be considered unless supported by independent evidence. The number of witches brought to trial declined precipitously.

In modern terms, y Frías had instituted a grand jury conflation between accusation and trial. Further, he had introduced rules of evidence which recognized the perverse and essentially meaningless forms which unstructured "facts" could take. Neither of these reforms has yet been introduced into major streams of the contemporary risk debate. And very few retrospective studies of the sort carried out by y Frías have yet been conducted by the modern risk assessment community.\* When we realize that y Frías' study occurred only after a century of active witch hunting, and that the practice was not completely stamped out until more than a century later, the prospect of rationalizing contemporary risk assessment seems distant indeed.

It is all very well to note the psychological and evidential problems which led the Church to protect its fold by burning godly numbers of them. But witch hunts continued as an organized political activity for over two hundred years, and it requires a certain credulity to pass off such persistence as a product of excess zeal and logical error. We may be forgiven for joining the lawyers in asking "Civil enough?" Who benefited from this complex, expensive, and destructive undertaking?

\*The invaluable studies of Lowless [10] focus on cases where a serious risk existed, but was recognized late. Missing are the complementary studies of legislative estimations where no risk existed. I discuss some retrospective looks in the matter of drug regulation below.

Anthropologist Marvin Harris has pointed out that to believe that the main purpose of the witch hunters was the annihilation of witches is to accept uncritically the lifestyle consciousness professed by the witch hunting community. Looking at "its earthly results rather than its heavenly intentions" [2, p. 237], the witch hunt supports a rather different interpretation. Whether individual witch hunters sincerely believed in what they were doing is not the point. As with risk assessment today, what actually happens may be radically different from what people think is happening. The benefits of our historical perspective on the witch phenomenon is that, with hindsight, we can see that difference, and try to learn from it.

To begin with, there was certainly an element of opportunistic careerism in the Inquisition, and there is almost certainly an element of opportunistic careerism in the present risk assessment movement. However small this element, it is clear that it can do a lot of damage to the world that the profession is trying to protect, and can bring the profession into disrepute in the process. The same reform Inquisitor Alonso Salazar y Frías who restructured the rational side of the witch hunt was evidently a worldly man as well. Besides instituting grand jury hearings and rules of evidence, he revoked the law that property of a convicted witch could be confiscated by the Church. Again, the rate of witchcraft accusations plummeted. It is interesting to speculate on what might constitute a similar perturbation experiment for today's risk assessors.

A second point illuminating the witch hunt phenomenon is that virtually no members of the clergy or aristocracy were accused, much less executed.\* At best, the profession was evidently incapable of coping with findings which refracted on itself. In fact, it reacted like a powerful elite which finds its own ox is about to be gored. One assumes that heretics accusing these privileged elites were promptly identified as the devil's agents. Anyone who has followed the recent debates over the risk of recombinant DNA research\*\* will recognize that things haven't changed much, and can imagine the outrage with which the Church must have reacted to accusations upon its own house. The same episode justifies a certain skepticism regarding the presumption that today's science community is willing to pursue its risk assessment activities into areas striking close to home.

A third historical issue is less firmly established but, for purposes of understanding the present, risk enterprise much more significant. Harris continues his analysis of the witch hunts with an argument that they functioned directly to increase the power of the elite institutions which conducted them, and simultaneously directed discontent against those institutions into relatively non-threatening channels.

The poor came to believe that they were being victimized by witches and devils instead of princes and popes . . . . Against the people's phantom

\*\*C.E. McIlwain, *Unsettled History in Socialization Grounds*, Stanford Univ. Press, Stanford, 1972) shows a ratio of 2:258 accusations between 1482 and 1684, 81% were female. Three members of the nobility were accused and none were executed.

\*For a review, see P.B. Hux, *Minor Research on Resemblance DNA: The Regulatory Issues*, South Calif. Law Rev., 31 (6) 1417-1426, 1975.

Reformers p. 311-313.

enemies, Church and State mounted a bold campaign. The authorities were unflinching in their efforts to ward off this evil, and the rich and poor alike could be thankful for the energy and bravery displayed in the battle. The practical significance of the witch mania therefore was that it shifted responsibility for the crisis of late medieval society from both Church and State to imaginary demons in human form . . . Not only were the Church and State exonerated, but they were made indispensable. The clergy and nobility emerged as the great protectors of mankind against an enemy who was omnipresent but difficult to detect [2, pp. 237-238].

Valid or not, there is an obvious modern parallel in this interpretation of the witch craze. Science has been under growing attack in recent years for a variety of ills ranging from wasting the tax dollar, to pompous arrogance, to greedily destroying our environment for short-term personal gain. The science establishment has recognized this, and governments are now funding grand programs on "research applied to national needs". Individual scientists, with all the good will in the world, speak of the need for "critical science" focussed on just such needs. If professional interests such as risk assessment continue on their present course, it will not be long before science can display its difficult and unimpressive efforts to ward off evil, its indispensability as "great protectors of mankind" against an enemy who is omnipresent but difficult to detect. This scenario does not require venality, but only self-interest and self-delusion. For that reason alone, it merits our attention.

To read too directly from the witch hunts of the 16th and 17th centuries to the risk assessments of the present would be to fall into the trap of historical determinism. To declare without further ado that "it can't happen here" would be to display naivete of another sort. At a minimum, as Trevor-Koper [1] has argued, the existence of the witch craze in the midst of the Renaissance is "a standing warning to those who would simplify the stages of human progress."

The "new professional interest of risk assessment" is not necessarily a progressive step. Neither its professed rational-scientific foundations nor its concern for collectively redressing ills of the human condition are enough, in themselves, to make it so. Both the potential for bettering human life and the potential for which hunting are latent in contemporary risk concerns. Our pressing task is to learn how we can cultivate one aspect of this Janus-faced creature while suppressing the other. In the next section I consider some more recent risk assessment experience which illuminates further aspects of this problem.

## RESOURCE MANAGEMENT: ON THE FUNCTION OF UNCERTAINTY\*

Some particularly useful insights on the basic nature of risk phenomena can be drawn from a consideration of man's attempts to manage environmental

\*This section is based on the work of my colleagues at the *Institute of Resource Ecology, University of British Columbia* [11, 12] and on the work of *Gilbert Walker, and Robert Kores's studies on man's relationships with environmental hazards* [13, 14, 15].

resources. The dual character of "risk" is again apparent. The river that brings water, irrigation, and transport also brings floods. The plants and animals with which we inhabit the earth provide us with oxygen, food, labor, and a variety of more subtle benefits. Under other circumstances, they may compete with us as "pests", attack us as diseases, or inconsiderately disappear under the various demands we place on them.

There is nothing witch-like or imaginary about the risks encountered through our relations with such resources. Failure to cope leads not to the ambiguities of future purgatory, but to the definite and immediate consequences of drowning, starvation, and consumption.

Anthropological studies have shown that pre-industrial "folk" societies adjust to such environmental risks largely through modifications of human behavior. From an external perspective, these adaptations often appear mystical and irrational. On closer examination, they often exhibit the notable virtues of being effective: a good deal of the time, of being flexible and easily adopted, of requiring action only at the individual or small group level, and of imposing little stress on the environmental system as a whole [13, p. 382, see also [6, 17]. Modern industrial societies have tended to pursue an opposite course of adaptation, controlling and reducing the variability of nature by means of large, long duration, capital intensive "engineering" projects. These have indubitably succeeded in achieving many of their short-term goals. But a look at the historical record shows that many of those gains have been bought in exchange for expensive and unanticipated long-term consequences. We have begun to discover that variability and uncertainty are in fact important "structural" factors, responsible in large part for the way our environmental and resource systems work. In general, they cannot be removed or reduced without precipitating major changes in those "workings". In particular, the control of small, frequent fluctuations has resulted time and again in a growing vulnerability to rare but large perturbations. Consider some particular examples.

Throughout the middle part of this century, the United States devoted unprecedented expenditures to the control of river flooding. By 1960, however, it was clear that the country's increasing flood control efforts were proving an ever rising level of flood loss and damage [18]. As might have been suspected, there followed a great deal of acrimonious debate amongst the flood-protection industries, Congress, flood victims, and sundry academies. The facts were denied, explained away, attributed to extraneous factors, and so on. But gradually there grew a body of evidence showing that the early technological view of flood risk protection had been seriously incomplete. People, together with their reactions to perceived flood frequency, had been left out of the picture. When empowerment and levee construction made former flood plains less prone to flooding, people reacted by moving into areas which now appeared "safe enough". Good control of normal river fluctuations was indeed achieved, and the previously farmed lands became more and more densely settled; their flooding history a more and more distant reality. When an exceptional flood eventually did exceed capacity of the flood works — or, much more rarely, when those works failed under less than their designed tolerances — the floods which resulted caused unprecedented damage [14, 18]. Only now are comprehensive strategies, incorporating the human element, beginning to be

devised. And these, almost without exception, are emphasizing mitigation and flexibility of response rather than the old litany of flood "control" [13].

A related phenomenon is documented repeatedly in the pest control literature. For example, in the period 1947-1974, agricultural use of insecticides in the United States increased over ten-fold. Over the same period, the rate of crop loss to insect pests rose by a factor of two [19]. In American corn production, while the acreage treated for pests has risen from 1% to 52%, crop losses have *ruen* nearly four-fold [19]. Nor can we simply stop using insecticides and hope things will go back to their original variable but endurable state of affairs. Though this might be possible in some theoretical long run, the short-term implications for farmers and food supply would be devastating. We are, sadly but simply, hooked on a risk control policy which gives us little, but which we can no longer do without. The broad result of our efforts to control pest risks has been to increase not only immediate damages, but also vulnerability to future surprises. There is no simple explanation for these seemingly perverse relationships. In some individual crops the results have been better. In others the losses are in part due to changes in tillage and usage practice which accompanied the increases of insecticides. But in many well-studied cases, it is clear that man's crude efforts to eliminate natural variability in the resource system are directly responsible for the ensuing debacle.

One such case is documented by Canadian studies of the spruce budworm [20]. Under natural conditions, this normally rare insect erupts into epidemics at intervals of 30 or more years, defoliating and killing a good proportion of the older coniferous forest as it does so. This forest destruction eliminates the insects' habitat, the outbreak collapses, and a healthy, young forest grows back in its wake. But these temporal uncertainties make efficient commercial utilization of the forest impossible, and insecticides were applied in control as an ineffectual eruption in the 1950's. By preserving the forest in a mature condition — by reducing its variability — this policy also preserved the biological conditions which precipitated the eruption in the first place. Today, under the relatively unvarying conditions of insecticide "control", budworms have spread throughout the entire province of New Brunswick where they persist at intermediate to high densities. Continuous, expensive applications of insecticides are required to prevent an epidemic. New forest and forest industry are more vulnerable, and at greater risk, than ever before, should the control policy fail or be abandoned. The most intensive analyses of this dilemma have been unable to design remedial policies with any but the most painful withdrawal symptoms.

Not surprisingly, a number of parallels to these pest-control histories can be found in man's efforts to control human diseases [11, 21]. The case of poliomylitis provides an especially illuminating example. It seems that prior to the 20th century severe cases of polio were rare. Minor infections were probably contracted by most children, producing immunity but few obvious symptoms in most. By the 19th century, however, improved living conditions and public health measures — in part introduced to combat cholera and other "unsanitary" diseases — had begun to isolate the more well-to-do segments of society from their traditional childhood exposures to various diseases. The reduced frequency of contact meant that these "diseases of cleanliness" were often first encountered in adult life, with violent or

# fatal results

This growing toll of polio cases, perversely focused on the most meticulously hygienic classes, fuelled the successful search for a vaccine. By the late 1950's, the incidence of polio was again extremely low in the United States and an organized scheme of inoculations was reaching a very large proportion of the school-age population. Once again, however, there is some suggestion that this "control" of uncertainty and fluctuation may well have increased vulnerability to large-scale disaster. Today, polio has become for many a threat of the distant past. Public health officials are finding it harder and harder to guarantee that significant proportions of the population are not missed by immunization and booster campaigns. It has been suggested that the growing complacency over the "non-risk" of polio may well be leading us to conditions which could support a major epidemic. The same is true for a variety of other diseases [see 11, 21].

Obviously, public health and vaccination campaigns have done a great deal of good, and will continue to do so in the future. But the reduced frequency of disease brought by vaccination programs is invariably accompanied by increased risks of other sorts. Such alternative risk structures — not the simplistic myths of natural exposure versus ultimate eradication — should be the focus of policy discussions and analysis in each particular disease case. Such explicit weighing of realistic alternatives has not penetrated in studies of humanly manageable variations for children as yet, in my point. Here, in exchange for protecting small children against a relatively mild illness, we leave adults susceptible to disastrous and debilitating attacks. It seems virtually certain that a broader perspective would encourage the disease in childhood, and vaccinate only adults who have missed natural exposure in their youth. As elsewhere, however, a simplistic and counterproductive prescription for "control" per se has so far prevailed.

The unpleasant surprises historically associated with efforts to manage pest and disease risks might be phased off as special consequences of introducing exotic substances into complex biological systems. But precisely the same sorts of unanticipated results have been encountered in apparently straightforward efforts to reduce the risk of forest fire in America's National Parks [2]. Once again, initial efforts were successful, leading to adoption of the policy throughout the park system. Only later did it become clear that brush and scrub unnaturally accumulated in the absence of small periodic fires were providing fuel for conflagrations of a size and intensity never before experienced. Again, "withdrawal" from the initially successful risk-reduction policy has been delicate and expensive in the extreme [11].

A final example of the relationships among uncertainty, risk, and resource management concerns the role of genetic variation. Studies in evolutionary biology have shown that variable environments give rise to populations with substantial genetic differences in traits relevant to the populations' survival. One genetic type will be slightly better adapted to one type of environmental condition, one to another, and so on. As a result, over a wide range of environmental conditions, disturbances, and surprises, some members of the population will do relatively well. The occasional variation in the environment shifts the balance and prevents one form from replacing all the others. It is true, however, that if environmental

conditions can be kept constant, one form highly adapted to those conditions will usually do better than a mix of forms. In agriculture, this situation has led to the breeding and distribution of genetically pure crop strains supremely well adapted to the controlled (low risk) conditions of water and nutrient availability which modern farms can provide.

A sobering lesson in the risks of such strategies was delivered to American corn producers in 1964 [23]. Huge tracts of land were by then planted in a single genetic strain of high yield corn. When a disease arose to which this particular strain was not resistant, a very large proportion of the crop was lost. Disaster was averted because some resistant strains were still available and could be used to replace the susceptible one. As a result of this and similar surprises, much more attention is now being devoted to the development and preservation of mixed genetic stocks in agriculture. The lower short-term yields obtainable from such approaches is judged an acceptable price to pay for the increased ability to cope with the unexpected.

Looking across these diverse examples of resource management experience, several common themes stand out. In each case, uncertainty or variability in the natural system was initially viewed as a source of risk/hazard. Without exception, it was assumed that removal of the variability would be an unmitigated good, resulting in reduced risk and improved performance of the resource system.

Initial successes led to optimism that the proposed management policy would be an effective one. But they also led to changes in the system itself. In each case, the existence of variability and uncertainty turned out to have played an important role in establishing and maintaining key relationships among the system components. With that variability removed, relationships shifted to accommodate the new reality: people settled the unlogged flood-plains, bulldozers spread through the undisturbed forest, brush accumulated on the unburned understory, and so on. As a result, the decreased frequency of variation in the system was accompanied by increased vulnerability to and cost of variation when it finally broke loose from managerial controls. Management efforts had changed the kinds of risks encountered, but not the fact of risk. And more often than not, management shifted the risk structure from one sort of people were accustomed to dealing with to one they had never before experienced.

Failures and surprises of the sort described here have been instrumental in sensitizing managers to the internal role played by variability in resource systems. Detailed investigation have begun to tease out the mechanisms involved in this sensitivity, and to let us make use of it in our policy designs (e.g. 11). But if we have learned something about the different structures which variation and uncertainty can take, our ignorance still remains more substantial than our knowledge. It is now clear that we are unlikely to reduce unpleasant surprises in resource management merely by increasing knowledge or imposing crude "controls".

<sup>1</sup>Unfortunately, it seems that we need to learn this lesson anew for each resource system. Present efforts to enhance the production of salmonid fish stocks in the Pacific Northwest seem likely to select for dangerously high levels of genetic variability in the future. See, for example, J. E. R. R. Bland, *Can. J. Fish. Res.* 31 (1974), 1851, 1859.

Rather, we must learn to design resource management schemes so that they can better cope with the failures which are guaranteed by our ignorance and the inherent variability of resource systems. This need for designing "soft-failure", uncertainty-tolerant management policies is receiving growing attention in areas beyond resource management [24]. Coupled with a concern for increased institutional flexibility, it forms the core of an approach to adaptive management which my colleagues and I at IASA and the University of British Columbia have been exploring over the last few years [12]. At the end of this paper, I will discuss some of the implications of this adaptive management notion for societal assessment of complex, incompletely known risk systems. First, however, I wish to consider one more set of historical lessons, this time taken from a field in which solid scientific knowledge of risk is at its most complete.

# DRUG SAFETY: THE LIMITS OF REGULATION

The history of drug development and regulation shows the risk assessment profession at its best. The problems in question are medicines destined from the beginning to combat specific ills of man and to improve directly his health and well-being. In return for their favors, medicines themselves pose risks, but of a very special kind.

First, exposure to the risk is limited to those seeking the related benefits. Second, the risk is undertaken in close consultation with a professional trained to help his patient balance personal risks, benefits, and alternatives in particular circumstances. Third, the nature of the risk itself has been carefully investigated, evaluated, and described through rigorous and sophisticated experimental investigations.

Each of these features of medical drugs should make their assessment and regulation easy relative to other risk situations. In fact, people dealing with nuclear, toxic chemical, or even traffic risks would almost certainly be thankful if even one of the properties listed above pertained to their systems. Looking at the history of drug safety efforts over the last several decades, we might therefore expect to learn something about the best that can be hoped for from risk assessments in other less mature and tractable fields.

This task is facilitated by the National Academy of Sciences' sponsorship a few years ago of a symposium with the familiar title "How Safe is Safe?". That symposium reviewed experience in the design of policy on drug development and regulation [25]. Papers were presented by a variety of senior drug regulators, producers, and consumers. With the recorded discussion, these papers provide a lively review of the current debate on drug safety issues. In so doing they raise serious questions regarding the limits of risk management. I review some of these below.

The basic procedures for risk-benefit assessments of medical drugs are well established. Preliminary screening makes use of extensive information and experience on similar products. Promising candidates move on to limited trials in lower animals, intensive evaluations in higher animal forms, and finally to closely supervised clinical trials on volunteer human subjects [26]. Real differences of

opinion arise not regarding the logic of this basic plan but on the judgmental issue of how much, and what kind of, assurance is needed before drugs are approved for human consumption.

If a drug is approved with minimal testing to make it quickly available to those who need it, people may be the guinea pigs who reveal unanticipated side effects. The specter of thalidomide is never far in the background when more rapid licensing procedures are debated. On the other hand, efforts to approach zero risk through exhaustive pre-release testing are extremely expensive and time-consuming. New drugs are delayed in reaching those who need them, and marginal drugs may not be developed at all.

Dilemmas of this sort exist in most risk management situations. The drug case is virtually unique, however, in that different solutions have been adopted in different countries, providing a prospect for empirical comparisons of regulatory efficacy. The two most thoroughly exercised and extreme solutions are those adopted by the United States and United Kingdom. The U. S. emphasizes intensive pre-market testing to mitigate the risk of unanticipated side-effects, while the U. K. promotes prompt release, relying heavily on an extensive system of post-marketing monitoring.

The explicit comparisons which have been carried out between these two approaches are in no sense definitive or free from methodological problems. With some unanimity, however, they conclude that the U. K. practice better advances the public interest [26, 27, 28]. American regulatory caution is argued to be needlessly expensive, stifling of new product development, and not superior in its ability to assure drug safety. In particular, the stringent safety testing procedures instituted in the United States following the Kefauver hearings and thalidomide episode of the early 1960's, are demonstrated to have been a mistake in classic risk-benefit terms [9]. The clear and vociferously suited conclusion of such studies is that some more rational form of regulation, including less expensive and time-consuming assessment procedures, is long overdue for the U. S. drug industry.

But while American drug regulators and risk assessors are being condemned as overly conservative by collective social welfare studies of the sort cited above, powerful, articulate, and convincing consumer groups are simultaneously attacking them for "caving in to industry" and neglecting their responsibility to assure the public's safety [e.g. 30]. Advocates of this position cite the regulators' failures to detect risks which "could have been" detected, and their ambiguous reactions to ambiguous evidence as proof that the public safety is too important to be left to even the best of safety experts. The beleaguered regulators have accepted consumer representation on their drug review panels, without anyone being sure just what those representatives are supposed to represent. Congress has responded to the political importance of drug safety by almost continual intervention in and reorganization of FDA. Significantly, however, Congress' direct attempts at

<sup>1</sup> *U.S. regulators have in the past been aware of the market potential for profitable products. Some of these may be literally a matter of life and death, but they have been able to find pharmaceutical concerns who market some "public interest" drugs on which they will never make a profit. Because of this, they have always been able to make some "highly profitable" drugs, not worth developing by even the most public spirited of concerns.*

"representative" safety regulation have resembled nothing so much as Keystone Cops scenarios (e.g. DES, saccharine). And Congress has failed repeatedly to meet FDA's own requests for an unambiguous legislative mandate specifying what balance of risks and benefits *does* constitute the public good, how this is to be democratically determined and achieved.

What emerges from the "How Safe is Safe?" debate in the drug field is that, for better or worse, public safety is now and is likely to remain a primarily political issue. Scientific data and economic analyses — even of the inordinately high quality encountered in the drug field — are simply not going to be the central issue in even the most technical of risk decisions.

This is not to say that science, data, and rigorous analysis are irrelevant to actual decisions in drug licensing. Nor does it suggest that carefully reasoned risk assessments do not have a role to play in other fields, even when these are destined to deal in even greater ambiguities of "objective" analysis than do drug safety trials. It does suggest, and strongly, that the would-be "professional interest of risk assessment" must reconsider its basic goals, and reassess its own potential for real contribution to the public interest.

One direction which such a reconsideration might profitably explore is suggested by Joshua Lederberg's "systems analytic" contribution to the drug safety symposium cited earlier [30]. He argues that contemporary safety testing procedures, even in the drug field, often resemble catechismal obstacle courses. These procedures undoubtedly do make it very time-consuming and expensive to introduce new products or proposals, but rarely has any effort been made to determine whether they actually do catch the hazards to which they ostensibly are a response. Some of the drug screening evaluations already cited in this section suggest that they often do not (e.g. 29). Furthermore, the cases I discussed in the earlier section on resource management suggest that simplistic or intuitively plausible "safety" measures may frequently increase total risk.

Lederberg concludes that we must come to treat the issues of drug regulation and management as problems of experimental design. Instead of routine adherence to large scale screening experiments on mice, or bizarre attempts to determine cancer "causing" dosages of some agent, he calls for "creative investigations that look for problems on the basis of some theoretical rationale" [31, p. 80]. It is the development of such rationales, rather than of arcane methodological treatments for eventually irrelevant data, which constitutes the central scientific challenge of contemporary risk assessment.

At a more prosaic level, Lederberg's call for an experimental design approach in drug safety regulation can be extended to the way in which we make use of experience and information that we already possess. The comparative evaluations of regulatory performance referred to earlier are valuable attempts to advance the public interest. On closer examination, however, they offer little actual policy guidance. Virtually no regulatory activity in any field has ever been shown to have a clean bill of health when subject to essentially economic evaluation [32]. To conclude from such analyses that we need "less regulation" or "deregulation" may not be wrong, but neither is it particularly instructive. The "don't regulate" vs. "do regulate" choice is a sterile and artificial one. To begin creating effective

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policies of risk management, we must surely begin to view these issues at a finer level of resolution. We need carefully designed studies to show what *kinds* of risks our present testing procedures can catch, and which kinds of risks they let slip by. Armed with such knowledge, we could begin to determine the kinds of tasks which various post-marketing monitoring schemes can perform effectively, and the kinds of situations where intensive pre-release investigation is justified. Only when we begin to blend the results of such studies in the careful design of integrated risk management strategies will we be able to move much beyond the present unsatisfactory state of regulation by polemic.

Finally, appropriate blends of risk assessment tactics are not likely to emerge from even the most sophisticated contemplation. We will have to learn to make efficient diagnostic use of the different empirical experiences emerging in different countries under different regulatory approaches. This brings us almost full circle to the notion of "adaptive risk management," already suggested by historical experience in resource management. In the final sections of this paper, I shall attempt to close that and other circles suggested by this survey of historical perspectives, and to suggest some general directions for future work in risk assessment.

## WHAT ARE WE ARGUING ABOUT?

The various attitudes towards the unknown suggested in my historical reviews were captured nearly a hundred years ago by Frank Richard Stockton in his studies on the ancient myth of *The Lady or the Tiger*:<sup>1</sup>

The young man could open either door he pleased. If he opened the one, there came out of it a hungry tiger, the fiercest and most cruel that could be procured, which would immediately tear him to pieces. But if he opened the other door, there came forth from it a lady, the most suitable to his years and station that His Majesty could select among his fair subjects. So I leave it to you, which door to open?

The first man refused to take the chance. He lived safe and died chaste. The second man hired risk assessment consultants. He collected all the available data on lady and tiger populations. He brought in sophisticated technology to listen for growling and detect the faintest whiff of perfume. He completed checklists. He developed a utility function and assessed his risk averseness. Finally, sensing that in a few more years he would be in no condition to enjoy the lady anyway, he opened the optimal door. And was eaten by a low probability tiger.

The third man took a course in tiger taming. He opened a door at random and was eaten by the lady.

<sup>1</sup>Stockton's initial translation of 1882 has been questioned on several grounds, but remains the most complete version available. I have used his work for the first paragraph quoted here, but for the rest of the more credible alternatives for its various endings, following the reasoning I developed in an earlier study of the myth [14].

Fortunately, none of this need present really serious obstacles to effective coping with the unknown. There is an alternative tradition of coping which, though virtually absent from the contemporary risk debate, has nonetheless long been a practical mainstay of successful coping in man and beast. This tradition accepts the inevitability of incomplete knowledge; seeks to accommodate rather than control the unknown, and thereby aims to coexist with and prosper from surprise. In this tradition, the "risk problem" is not uncertainty of outcome, or violence of event, or toxicity of substance, or anything of the kind. Instead, it is the challenge of coping confidently, effectively, and creatively with the surprising world around us. The fundamental question is not how to calculate, control, or even reduce risk. It is how to increase our risk-taking abilities.

Nowhere is this distinction clearer than in the questions of medical drug safety which I reviewed above. By any imaginable criteria, the complex, biologically active compounds generated by modern pharmaceutical concerns are risky things indeed. The sheer volume of production is frightening enough. Add the high proportion of that production that comes into contact with humans and you have a situation bound to dispatch a modern risk assessor for his inunctions and press agents. In the medical drug case, however, the existence of a professional managerial framework within which these dangerous chemicals are characterized and administered and monitored makes them into risks we can afford to take, thereby improving our health and well-being. Any narrow attempt to create a world free from the very real risks posed by such chemicals would entail obviously unacceptable consequences. Moreover, since many drugs are now more risk-benefit accounting would produce similarly unfortunate results. In contrast, improve-ment in our ability to take risks — in our knowledge of how the drugs confer their risks and benefits, in doctors' and patients' understanding of the trade-offs involved, in the monitoring and diagnosis of unanticipated (positive and negative) drug reactions — will increase our capacity to cope with disease and improve our health.

A similar emphasis on increased risk-taking abilities, rather than decreased risk per se, emerges as a strategy for coping with the unknown in a number of pragmatic fields which have tried the alternatives. Portfolio designers long ago recognized the fallacies of "risk-free" earning strategies [36]. Boehm-Bawerk's Law based on one of the most rigorous theorems in economics, states that existing means of production can yield greater economic performance only through greater uncertainty — i.e. through taking greater risks. Strategic corporate planning has been defined by one of its most successful advocates as creating the "capacity to take a greater risk, for this is the only way to improve entrepreneurial performance" [37]. Most biologists, myself included, would concur with W. H. Auden's poem "Unpredictable but Providential", wishing only that we had put the central experience of our discipline so well:

... for the animal, to last was to mean to change,  
existing both for one's own sake and that of all others,  
forever in jeopardy . . . .

As a rule it was the fittest who perished, the misfits,  
forced by failure to emigrate to new unsettled niches, who  
altered their structure and prospered . . . .

Rene Dubos states the biologist's conclusion more bluntly [38]: "Willingness to take risks is a condition of biological success." This point is critical to our understanding of human risk-taking. Willingness to take risks, together with knowledge of risk-taking consequences, determines our ability to cope with the unknown. Confidence is as important as understanding if we are to shape the future in a rational way. The real challenge for the "new professional interest in risk" is to contribute to build

In seeking to meet this challenge, it is reasonable to begin with the paradox of contemporary social risk history. The more we learn about risk the less confident we seem to be of our risk-taking abilities. Hence we have the spectacle of an American society which has a greater life expectancy, higher level of material welfare, and more knowledge than ever before, frightening itself into virtual catatonia, unable to mobilize the risk-taking efforts necessary for coping with the unknown. A "new professional interest in risk" which cannot bring itself to address, much less explain, such a central fact of its subject is hardly a thing to inspire confidence.

Nobody knows what makes one individual or society believe in itself while another heads for the bunkers.\* After all, Columbus was venturing into the void at the same time Institoris and Sprenger were inciting witch hunters to new heights of paranoia. It seems virtually certain, however, that risk assessors' sincere knowledge-seeking efforts to identify potential dangers can undermine the very confidence which would be necessary for creatively coping with those dangers. The proverbial "little knowledge" is both a dangerous and a frightening thing. We have already seen the workings of this in the witch hunts of the Renaissance. Authoritative and, let us presume, sincere preachers preached valiantly the dangers of witches and of the devil's incredibly subtle and cunning ways of infiltrating society. In so doing, they amplified society's latent fear of the

\*For some puzzling thoughts on the subject, see Gardner [39].

unknown, undermined its confidence, cohesion, and common sense, and thereby contributed to the public hysteria which later fuelled the excesses of the Inquisition. Today, authoritative and, let us presume, sincere scientists preach valiantly the dangers of risks and their incredibly subtle and cunning ways of infiltrating society. The Chief Counsel of the Food and Drug Administration admits "we often regulate more out of fear of the unknown than out of respect and appreciation of the known" [40, p. 133]. Society's attitudes towards risks such as cancer and nuclear reactors are not readily distinguishable from its earlier fears of the evil eye.

This is not to say that today's society does not face real risks, nor to deny the real accomplishment of risk management professionals in dealing with those risks. It is to insist that the dual character of the coping problem — the need for knowing and willing — is virtually ignored in contemporary literature on the risk problem.\* Preoccupied with the knowledge aspects of early warnings and assessments, we are caught inside the risk problem and become part of it. Unable to see the relationship between our knowledge-seeking work and the fear of the unknown, it may engender, our contributions to the real problem of enhancing society's risk-taking and coping abilities are correspondingly dissipated or flatly counterproductive.

The challenge of establishing a rational perspective from which to view risk problems and our interventions in them is, however, greater than merely coming to understand the relationship between fear and knowledge.

Alvin Weinberg provided the glimmer of such a perspective in his concept of "trans-science," first enunciated in a discussion of "How safe is safe enough?" for nuclear reactors [41].

Attempts to deal with social problems through the procedures of science hang on the answers to questions which can be asked of science and yet which cannot be answered by science. I propose the term *trans-scientific* for these questions. . . . Insofar as public policy depends on trans-scientific rather than scientific issues, the role of the scientists in contributing to the promulgation of such policy must be different than its role when the issues can be unambiguously answered by science. . . . When what we do transcends science and when it impinges on the public, we have no choice but to welcome the public — even encourage the public — to participate in the debate. Scientists have no monopoly on wisdom where this kind of trans-science is involved, they shall have to accommodate the will of the public and its representatives.

What is this "different role" required of the risk scientist? How is he to promote scientific knowledge without spreading social fear? How is the "will of the public" to be accommodated in risk problems? Neither Weinberg nor anyone else has proposed definitive answers to these questions, but in the last several years several lines of inquiry have been opened

\*The problem is not unique to risk studies. Lindblom [42] distinguishes between the knowledge-based preferences which inform economic theory, and the will-based valuations which, together with preferences, inform political choice. In a pioneering essay on the nature of useful knowledge [43], he characterizes these two temperaments as *forms of rational evaluation as "thinking through" and "acting out"*.

In reviewing these, it seems to me that there are two distinct if related issues at stake. One concerns the incompleteness of scientific understanding which can be brought to bear on risk questions. The other involves the conflicts of individual wills, values, and freedoms which bear on those questions.

#### TOWARDS THE ADAPTIVE DESIGN OF RISK MANAGEMENT POLICY

Let us first consider the problem of incompleteness. In mature academic science, the incompleteness and fallibility of knowledge should cause no fundamental difficulties. Theories are held tentatively, contingent on new evidence. Contrary evidence and new interpretations are granted equal access to the debate. Independent experiment and peer review provide checks and balances against error and unscrupulous behavior. Of course the ideal standard is often bent or broken in practice, but in the long run, in the majority of cases, good science does seem to replicate itself.

This is not the case, however, in what historian Jerome Ravetz has called the less developed or "immature" sciences, especially when those sciences are applied to social problems [45]. In such circumstances a variety of factors conspire to suppress tentative outlooks and to settle on incompleteness as an excuse for polarization. The result is bad science, leading to unnecessary public alarm, unjustified and ineffective regulations, and an unwillingness to undertake the risk-taking ventures necessary for coping with the unknown [46].

In part, the phenomenon can be explained in terms of a breakdown of quality control within the scientific discipline. The relative absence of established facts or criteria of competence tends to make peer review ineffective. Add the pull of a socially relevant, "public interest" discipline, and there is a real danger that the field will experience "an accretion of cranks and congenial rebels whose reforming zeal is not matched by their scientific skill" [45, p. 427]. Where recognition and grant money both accrue to those making the first, loudest, and most frightening noises, where accusations of corruption, cowardice, or insensitivity are the most likely rewards of the careful skeptic, then the "great confidence game" portrayed by Ravetz cannot be far off.

The fault, however, does not all lie with science. Harvey Brooks has pointed out . . . an interesting parallel between the scientist's desire to establish priority for a discovery or invention, and the politician's search for new issues on which he can make a name for himself. . . . The potential alliance between individual politicians and scientists, though often beneficial, can also be dangerous because neither side is subject to the normal checks and balances of peer groups. Once a politician has staked out scientific territory for himself, his colleagues tend to stay away. At the same time the scientist is speaking in a forum to which opposing scientific views are not more or less automatically accorded equal access. The politician is free to select his own

<sup>10</sup>Unfortunately, it also often displays the merely different. For a particularly readable and disturbing account of *Intergovernmental Incompetence in Modern Science*, see Fryxell [41].

experts to develop an issue in the way that has maximum political utility to him. Truth may be only incidental [47, p. 259].

Even the most conscientious risk scientist, trying to present a balanced view of a complex and uncertain issue, is likely to find his argument caricatured and polarized in such a process. Brooks continues

Scientists inexperienced in the political arena, and flattered by the uncensored attentions of men of power, are often inveigled into stating their conclusions with a confidence not warranted by the evidence, and . . . not subject to the same sort of prompt corrective processes that they would be if confined within the scientific community [47, p. 259].

While these and other problems of the incomplete scientific knowledge in risk matters are widely recognized, most responses have essentially called for a resolution through better science. This misses the central issue completely. Thus we have the 1976 Bellagio Conference on Science and Technology calling for the scientific community to "evolve and sustain new standards of scientific rigor appropriate to research in support of early warnings and policy decisions" [49, p. 33]. Or, for those with less faith in their fellow scientists, there are the science court proposals for what amounts to super-peer review [50]. In both cases, the underlying assumption seems to be that rigorous science, or rigorously reviewed science, would not be subject to the incompleteness, polarization, and exploitation that characterizes risk science today. With all respect to good intentions, the historical experience of risk management<sup>10</sup> makes this assumption hard to accept. An alternative, or perhaps complementary, response to the incompleteness dilemmas of trans-science is provided by the growing craft of policy analysis. In a recent *Science* editorial on the subject, M. Granger Morgan argues

Good policy analysis recognizes that physical truth may be poorly or incompletely known. Its objective is to evaluate, order, and structure incomplete knowledge so as to allow decisions to be made with as complete an understanding as possible of the current state of knowledge, its limitations, and its implications [51, p. 971].

Policy analysis of the sort Morgan describes is just beginning to emerge from its uninspiring past as a branch of applied mathematics. There are indications, nonetheless, that it does indeed offer a realistic and rational perspective from which Weinberg's trans-scientist can shape his "different role" in the social risk debate . . .

<sup>11</sup>Brooks draws the latter part of his suggestion from the studies of Nelson [48].

<sup>12</sup>The difficulties encountered in scientists' statements to the media are similar in kind and origin, and even more intentional in outcome.

<sup>13</sup>I would argue, for example, that risk management of medical drugs already has both the "vigorous standards of biology" and the super-peer review of the science courts. The debate is none the less acrimonious. Wilentz [53], p. 2.

<sup>14</sup>The remainder of this section draws heavily on the concepts of policy analysis as developed by J. R. Wilson [53], p. 2. For another more formal view see Quade [53].

In some ways, this role seems likely to take on more the character of a jurist than a traditional positivist scientist. Policy analysis recognizes, above all else, that "the data" are always insufficient to dictate unambiguous conclusions. Rather, particular data are generated, selected, and inserted into an argument as evidence in support of a particular conclusion [32]. The listener may be persuaded by the force of the argument and the strength of its evidence. But there is no suggestion that data themselves are either necessary or sufficient to a given conclusion. The debate therefore shifts away from a preoccupation with "facts" and their "proof". It turns instead to the careful development of rules for the admissibility of legitimate evidence, and for the form of legitimate argument. Such rules are known to be fallible — the guilty can be acquitted and vice versa — but fallibility is accepted as an inevitable consequence of our lack of omniscience. On the other hand, careful attention to developing mutually agreed-upon rules of evidence can create that essential willingness to proceed in the face of fallibility. It has done this for drug regulation, and our health is the better for it. Attention to rules of evidence can also assure against the wider tyrannies of self-evident "fact": where no effective peer review exists. It did this in Alonso y Frías' reforms of the Inquisition's torture and indictment procedures. Perhaps most important, formal rules of evidence constitute formal hypotheses on how we can best cope with the unknown. Viewed in this manner, they invite us to use our continuing experience in risk management to evaluate our present rules, and to suggest improvements in them. We therefore can learn from both our successes and our failures and hope for some cumulative improvement in our risk-taking, surprise-coping, abilities. Contemporary risk management's inability to effect such cumulative improvements, its insistence on re-fighting all the old battles with each new risk issue, is one of the most discouraging aspects of its exclusively "fact"-focused approach.

The notion of learning from error is central to modern policy analysis, as it is to those pragmatic coping strategies of man and beast which I outlined earlier. The litany goes something like this. If knowledge is incomplete, if the future is uncertain, then mistakes and surprise are inevitable. The categorical imperative is to recognize such mistakes, to learn from them, and to modify future actions accordingly.\*

In this view of life, rationality becomes a retrospective but still respectable concept. Since actual performance is contingent on facts unknown, futures unborn, and choices we ourselves have yet to make, the "rational" is evident only in retrospect. It is what turned out to be adapted to the conditions that occurred, and turned out to be adopted by the powers that were [32].

The problem of rational management is therefore to design self-evaluating policies which adapt themselves to the developing situation and, in so doing, cultivate the will necessary for their adoption and continuing pursuit. Such a reconstructive concept of rationality is central to evolutionary (as opposed to teleological) thinking in a number of fields [32]. Its appropriateness as a guide to action has been argued in terms of social psychology [36], economic theory [37], and the pursuit of scientific endeavor [38]. Furthermore, as Kujawa points out,

*"It has been said that a fool makes many mistakes, while a demon fool makes only one. Over and over again*

This explanation makes sense of behavior frequently observed among policy makers — such as incrementalism, adaptive adjustments, imitation, and "rationalizations" — which must appear to be irrational and/or dishonest in the prevailing models of policymaking [52, p. 215].

Those "prevailing models", unfortunately, are the ones which inform a good portion of contemporary risk management activity. The synoptic planners, cost-benefit analysis, and regulatory bureaucracies seem wedded to prospective, knowledge-presuming notions of "rationality" in policy making "Optimal" or "best possible" decisions and decision-rules are derived on the basis of available information, and implemented by virtue of their rationality (social optimality, expert consensus). Subsequent performance can be taken for granted, provided always that compliance with the rational rules is rigorously enforced.

If this sounds too extreme a caricature of present practice, try any other one that comes to mind. Michael Crozier, in his classic study of *The Bureaucratic Phenomenon*, defines bureaucracy as "an organization that cannot correct its behavior by learning from its mistakes" [59, pp. 186-187]. Regulation by such bureaucracies has become almost synonymous with risk management in America today. From the policy analysis perspective, with its insistence on an adaptive, "error-embracing" response to the unknown, it therefore comes as no surprise that risk management is in trouble. More constructively, policy analysis suggests that effective, rational coping behavior may depend more than anything on our ability to design flexible, adaptive management institutions. Institutions which can respond to and learn from the inevitable surprises awaiting us. Institutions which can mobilize public will in risk-taking enterprises. Institutions which can improve our ability to cope with the unknown.

Explicit policy analysis focussed on design of alternative institutional structures for risk management has barely begun. The sterile debates over "regulate" versus "don't," "threshold" versus "root", and the like have so far occupied center stage and most of the wings [32]. Some of the notable exceptions include Michael's [60] and Thompson's (this symposium) studies from the human behavior perspective, the comparative risk studies I referred to in the discussion on medical drug regulation, plus those of which I reported elsewhere in this symposium, the explicit policy analyses of Malone [61, 62, 63], and the applied work being done under the several banners of "mediation" [64, 65]. These suggest a productive future for policy analyses of risk problems and their institutional settings, if only the debate can be turned in the constructive directions they have suggested.

What that future will be like I am not so silly as to suggest in a paper emphasizing uncertainty and surprise. My personal favorite for attention concerns the "scale" of our risk management institutions and arrangements. There is a strong tendency

\*The term is from M. Crozier's [60] insightful study of the human aspects of Learning to Plan and Planning to Learn.

\*\*Significantly, this was also the overriding need identified by the previously mentioned Bologna Conference on Science and Technology. See [34].

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## ACKNOWLEDGMENTS

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## CLARK

today for every fear, every unknown to be met by mandatory regulation at a national or even supernatural scale.

This approach might possibly be justified in a world where one socially optimal regulation could be computed in advance, or where the externalities of local risk-taking decisions would be truly national in scope and unbearable in effect. It might, in general, be justified if everyone wanted it. But in most cases of risk management, not one of these conditions is met.

An opposite extreme, less well explored, is a variation on the thousand flowers blooming approach to cultural revival. I suspect a careful policy analysis would show that maximal social learning and political will could be mobilized by designing the scale of particular risk management ventures to fit the character of the risk under consideration. Thus while we might require regional scale regulation in such externality-laden fields as air quality management, we might find that much smaller scales — and therefore more, different learning experiments and less compulsion — would be appropriate in other cases.

Medical drugs, for example, would seem to present the perfect situation for experimenting with much more "local" autonomy in risk management decisions, even down to the level of the individual. My finer fancies imagine the Generally Recognized as Safe (GRAS) list of drugs being complemented by one General User's discretion, with a full description of the known risks and benefits available as advice, but a minimum of absolute constraint. The liabilities issue would be difficult, but could doubtless be resolved with sufficient ingenuity. Appropriate, perhaps, would be voluntary "de-socialization" of the risk in the form of an agreement not to hold the manufacturer accountable or insurance agencies liable for adverse effects. I can imagine circumstances under which I would agree to such conditions, just as I can imagine preferring the de-socialization of communication to the alternative of a witch trial.

The more general point is that to the extent that large-scale monolithic regulations can be avoided, "local" risk-taking preferences can be left to run their course as experiments in risk management. Government can shift from its stressful role as incompetent regulator into a more congenial role as broker of information. Is California's (or San Francisco's, or J. Fred Muggs's) approach to Laetitia working better than New York's? In what ways? Who has a third approach? And so on.

Note that the apparent ethical dilemma in fact is less than it seems. If we really don't know how to manage a risk, then we're all guinea pigs. The fight over whose expert to believe can be transposed into a contest over whose expert guessed better, and learns faster.

The challenges of helping to design alternative — even competitive — coping strategies and institutions, of evaluating and comparing their actual performances, and of redesigning adaptively in response to what is learned should be enough to satisfy the most ambitious of risk policy analysts. They might even help to make the future of risk management a more satisfactory endeavour than its past and present.



The CHAIRMAN. Thank you, Mr. Kazman.

Our next witness is Mr. Scott Holman, who is president and CEO of Bay Cast, Incorporated. It is my understanding that—yes, he is your constituent, Mr. Barcia, and we would welcome you introducing him.

Mr. BARCIA. Thank you very much, Mr. Chairman.

It is a great privilege today to introduce Mr. Scott Holman to the Science Committee. Mr. Holman is a highly successful businessman and a constituent, someone who employs the notion of hard work, determination, and a single-minded pursuit of excellence in his day-to-day business as well as his personal life. Mr. Holman lends his expertise in developing and maintaining a profitable small business in today's regulatory environment from a wealth of practical experience.

In 1987 Scott founded Bay Cast Technologies, presently the leading designer and manufacturer of test support and alignment systems and consistently ranks as one of the best companies in Michigan. Also in 1987 Scott acquired assets of the defunct Bay City Foundry and established Bay Cast, Incorporated, presently the leading producer of large custom steel castings for the mining, steel mill, construction, automotive, and machine tooling industries. In his first three years at Bay Cast, Scott tripled sales from \$3.2 million to \$9.5 million and reemployed a once closed Bay City plant with 90 workers.

In 1990 Scott was named the national turnaround entrepreneur of the year by Inc. Magazine, Ernst and Young, Merrill Lynch, Keenan Institute, and the Institute of American Entrepreneurs. Scott is on the board of directors for the Institute of American Entrepreneurs, the U.S. Chamber of Commerce, on behalf of whom he is speaking this morning, and as a member of the National Small Business Council.

Mr. Chairman, and fellow members of the Science Committee, it is with great pride that I introduce Scott Holman to those gathered here today and again thank you for the opportunity to do so.

Mr. Holman, I look forward to your testimony.

The CHAIRMAN. Mr. Holman, we do invite you to give your testimony, and we are extremely glad we have invited you after that glowing introduction.

Mr. HOLMAN. Well, that was very kind. Thank you Congressman Barcia.

Good morning, Mr. Chairman and members of the committee. I am very pleased to be here to offer a small business perspective on the subject of risk analysis and the need for regulatory reform. I do ask that my full written statement be a part of the permanent record.

I am testifying on behalf of the U.S. Chamber of Commerce and its more than 215,000 members, where I serve on the board of the directors, its Regulatory Affairs Committee, and the Small Business Council, as well as for the American Foundrymen's Society, the leading trade association for the metal casting industry in North America.

While not an expert theorist on risk analysis, I am a practicing expert on cost-benefit analysis and risk assessment, as are most surviving entrepreneurs. If I fail to set priorities based upon well

grounded information, I risk not being able to make my payroll. If I fail to make an appropriate risk assessment, I can lose the order that may keep my people working or, worse, I may get the order that can place my whole operation at risk for its very survival. If I fail to use well founded plausible assumptions in the allocation of my limited resources and commit capital in the wrong area or at the wrong time, that's all there is and I can't get it back.

I know a great deal about the power of information as a tool in decision making as well as the need for priority setting for any organization that seeks continuous improvement into the future. In a word, the free market system makes me brutally accountable for my decisions. I want a clean, safe, healthful environment, not just because somebody imposed the regulation or even because it is morally correct. My employees, who are just like you and I, perform the way they feel, and they feel the way they perceive themselves, and they perceive themselves in the context of their surroundings. That means that their working environment affects their performance. So we in the industry have a common goal with the regulatory system that attempts to ensure a clean, healthful, and safe environment, but that system is in desperate need of improvement.

The burdens for small business go far beyond the direct costs of compliance. Most of us cannot afford to have a full or even part-time environmental staff in house and therefore face escalating costs of consultants and attorneys to comprehend our obligations under the hailstorm of regulations: Are we tailoring our laws to the actual risks out there? Which regulations are justified, those that make an appreciable difference in our health and quality of life or those that force us to jump through new hoops and pile up paper and consume capital and human resources with questionable results?

The risk provisions in title III of H.R. 9 would strengthen the use of risk and cost-benefit analysis and lead toward developing higher quality decisions by our regulators.

The foundry industry no longer finds itself competing on a regional basis. Bay Cast, for example, depends on a North American and European market for a significant share of its business. Conversely, our competition, both in domestic and European markets comes, from China, the Czech Republic, and other countries with emerging industrial economies with cheap labor whose governments not only supply capital and subsidize their production but do not impose the stringent environmental health and safety regulations by which we are governed.

Risk policy therefore affects my own company in many ways down to the most mundane conventional materials used in my industry. The sand we purchase, for example, to make molds for casting metal is considered a cancer-causing substance that requires at minimum a hazard warning label and paperwork to be filed with the local and State agencies. Disposal mandates and beneficial reuse restrictions unnecessarily consume millions of cubic yards of valuable landfill space as well as our dollars for something that could be a resource. Independent studies indicate that if risk analysis were done it would show that over 90 percent of the foundry's sand is safe and could be made available for recycling or other commercial uses.

I believe that improving the use of risk assessment and making data and assumptions more transparent will produce a well informed decision-making and build the confidence of the public that the most serious problems are being addressed. I believe that strengthening the role of cost-benefit analysis in regulation gives us a better picture of the critical incremental costs of more protection. And, finally, I believe that expanding the role of peer review will lend more credibility to the assessments of our health and environmental challenges. All of these things are vital to win back the confidence of small business in a regulatory system that now suffers from a serious credibility gap.

Title III is a pragmatic and measured attempt to correct the real flaws in our system without giving up the protection the public wants. I, for one, do not want to poison my workers or my neighbors or destroy the beauty of my community, and I have no interest in paralyzing our regulatory system with hurdles and delays, but we need accountability and a departure from the status quo because small business in this country can no longer afford the tremendous economic costs of distorted priorities.

We have a moral obligation to face up to the trade-offs that are part of living in this world and that are necessary in an era of scarce resources. This legislation forces a degree of feet-on-the-ground accountability through risk analysis, cost-benefit analysis, open communication, contextual comparison, and peer review. Ultimately reasonable people of good will can disagree on the details, but the overarching and powerful concept of this legislation must be given a try.

Thank you.

[The prepared statement of Mr. Holman follows:]



# Statement of the U.S. Chamber of Commerce

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**ON:           TITLE III – RISK ASSESSMENT AND  
              COST/BENEFIT ANALYSIS FOR NEW REGULATIONS**

**TO:           HOUSE COMMITTEE ON SCIENCE**

**DATE:       JANUARY 31, 1995**

**BY:           SCOTT HOLMAN**

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The U.S. Chamber of Commerce is the world's largest federation of businesses and associations and is the principal spokesman for the American business community. It represents more than 215,000 businesses and organizations, including 3,000 local and state chambers of commerce, 1,200 trade and professional associations, 72 American Chambers of Commerce abroad, and 11 bilateral international business councils.

More than 96 percent of the Chamber's members are small businesses with fewer than 100 employees, 71 percent of which have fewer than 10 employees. Yet, virtually all of the nation's largest companies are also active members. We are particularly cognizant of the problems of smaller businesses, as well as issues facing the business community at large.

Besides representing a cross-section of the American business community in terms of number of employees, the Chamber represents a wide management spectrum by type of business and location. Each major classification of American business -- manufacturing, retailing, services, construction, wholesaling, and finance -- numbers more than 10,000 members. Yet no one group constitutes as much as 32 percent of the total membership. Further, the Chamber has substantial membership in all 50 states.

The Chamber's international reach is substantial as well. It believes that global interdependence provides an opportunity, not a threat. In addition to the 72 American Chambers of Commerce abroad, an increasing number of members are engaged in the export and import of both goods and services and have ongoing investment activities. The Chamber favors strengthened international competitiveness and opposes artificial U.S. and foreign barriers to international business.

Positions on national issues are developed by a cross-section of Chamber members serving on committees, subcommittees, and task forces. Currently, some 1,800 business people participate in this process.

STATEMENT  
on  
TITLE III-RISK ASSESSMENT AND COST/BENEFIT ANALYSIS  
FOR NEW REGULATIONS  
before the  
HOUSE COMMITTEE ON SCIENCE  
for the  
U.S. CHAMBER OF COMMERCE  
and  
THE AMERICAN FOUNDRYMEN'S SOCIETY  
by  
Scott Holman  
January 31, 1995

I am Scott Holman, owner and CEO of Bay Cast Inc. My company is a small, Michigan-based manufacturer of large custom steel castings for the automotive tooling, machine tool, steel mill, mining, and construction industries, with 90 employees. I am pleased to present this statement to the House Committee on Science on the subject of risk analysis and the need for regulatory reform.

My testimony is on behalf of the U.S. Chamber of Commerce and its more than 215,000 members, where I serve on the Board of Directors, the Regulatory Affairs Committee, and the Small Business Council. I am also testifying for the American Foundrymen's Society (AFS), which is the leading metalcasting association in North America. The society was founded in Philadelphia in 1896 and has nearly 14,000 members from 49 states across the nation. AFS provides leadership in technical developments and research; education and training; marketing; management; human resources; and government relations.

AFS sponsors research in the areas of casting processes, product quality and design, and environmental, health and safety. Such research is supported by technical committees comprised of 800 volunteers from across the industry. The Society publishes 100-150 technical papers annually along with hundreds of handbooks, textbooks, and reference books, making it the world's largest publisher of metal casting-related materials. AFS is the recognized source for technical and management services to the metal casting industry in America.

Small business strongly supports the effort to make risk-based decisionmaking a priority for the new Congress through passage of Title III of H.R. 9, the Job Creation and Wage Enhancement Act of 1995. The provisions of Title III would strengthen the use of risk and cost-benefit analysis and lead toward the development of higher-quality decisions by regulators.

I am not an expert in theoretical models and statistics, but I am an expert in risk analysis. As an entrepreneur, I practice risk analysis in the trenches every day. I know a great deal about the power of information as a tool in decisionmaking, as well as the need for priority-setting for any organization that seeks to improve itself into the future. I want a clean and healthy environment just my colleagues in the business community at-large — I want to maintain a safe workplace for my employees. However, the current regulatory system is in desperate need of improvement.

The examples I cite here are, of course, from my own industry. However, many of my colleagues in the business community have told me of their own, parallel examples of how the nation's economy and competitiveness are being hamstrung by inattention to appropriate risk analyses and risk management.

#### **Small Business Support for Title III: The Need for Clarity and Matching Resources to Threats**

Title III provides the opportunity to address affirmatively some key issues regarding the science behind regulations and the competitiveness of small business in the United States. Are we tailoring our laws to the actual risks incurred by the public? Which regulations are justified — those that make an appreciable difference in our health and quality of life, or those that force us to jump through new hoops and pile up paper, yet do not make us any better off?

**Sections 3104/3105:** Sections 3104 and 3105, requiring clarity in risk assessments and risk characterizations, will give the public an improved understanding of the scientific and technical basis for the regulations. The requirement that federal agencies provide risk

comparisons may eventually drive agencies to use comparative risk analysis to prioritize risks and allocate limited public and private resources to maximize protection of human health and safety and the environment.

**Section 3201:** The provisions of Section 3201, which mandate a risk assessment, a cost-benefit analysis, and a certification of scientific and technical credibility for every major new rule relating to human health, safety and the environment, will improve the quality and effectiveness of federal regulations.

This legislation is not, as some critics have charged, a giant step backward that would put our regulatory system in chains and diminish the protection of public health and the environment in our communities. If anything, it is a collection of very courageous and forward-looking ways to do a better job of matching our resources to our most pressing problems. It is a framework that helps us to have a more open and honest dialogue about what we are getting for our money.

### **The Challenges Facing Small Business**

Small business faces a unique set of competitive challenges in the 1990s that are not readily accommodated by our current regulatory system. Our foreign counterparts are often granted more flexibility to meet their environmental responsibilities, when they are regulated in any significant way at all. They also receive more favorable tax treatment by their governments when they make investments in pollution-control equipment.

Small businesses in the United States are not afraid to compete in the global economy under these conditions. But many smaller companies, even those led by the most innovative and visionary management, can only be as productive and efficient — and therefore as competitive — as our regulatory constraints allow. Yet there are numerous examples of regulations that stifle needed productivity growth because they do not — or cannot under statute — adequately take risk into account.

This is not an argument for turning back the clock on every existing regulation that affects on productivity. There are clear cases where appropriate tradeoffs must be made in favor of public health protection and the environment. In that vein, Title III does not permit changes to current laws and regulations that might, for example, "fail" a cost-benefit or risk-benefit analysis. Rather, it simply puts in place some basic tools and procedures to get crucial information to policymakers, regulators, and the public about the choices we make, the level of risk reduction our regulations achieve, and their attendant costs.

Title III would impose a minimal set of demands on the regulatory system. Fundamentally, it would increase accountability in our federal agencies, and points out where the competitive edge of small business might be compromised by regulations that fall short of achieving meaningful protection for our citizens. The actual policy decisions to reprioritize and actually shift resources among programs and agencies to buy more effective risk-reduction will have to be made independently by our lawmakers and our chief regulators. The critics of this legislation should recognize its limited scope.

#### **The Scientific Rationale for Regulation: "Is Sand Poison?"**

In the area of the scientific rationale for regulation, risk policy affects my own company in many ways, down to the most mundane, conventional raw materials used in metalcasting. Even regular sand, which we purchase to make molds for casting metal, has been found by researchers to cause tumors in laboratory rats, and is thus considered by some authorities to be a cancer-causing material to humans. This is the same material that our children play with in the sandbox. This is the same material we sit on at the beach.

Based on as few as two rat studies and very limited epidemiological evidence, the International Agency for Research on Cancer (IARC), an arm of the United Nations, has classified sand (crystalline silica) as a probable human carcinogen without even performing a formal risk assessment.

IARC emphasizes that its cancer listings should not be used as a basis for regulation. However, the United States is one of very few nations in the world to incorporate automatically IARC's cancer classification into major statutory and regulatory requirements for U.S. businesses. These regulations require — at minimum — hazard warning labels on bags of sandbox sand, and for my industry, special paperwork to be filed with local and state agencies to notify them that we are storing and using a dangerous material. California EPA (Cal-EPA) in particular has taken regulatory scrutiny of environmental exposures to sand a step further, and Michigan has recently explored the issue of human health effects from ambient exposures to silica.

In California, regulators performed a quantitative risk assessment to measure — and ultimately attempt to reduce — the potential dangers to public health from sand emitted from foundries, small gravel operations, or other sources adjacent to residential areas. The risk assessment performed by Cal-EPA produced an acceptable level of exposure to the public which, if used in regulation, would call for the reduction of sand emissions from industry to levels far below what a person would normally be exposed to in the environment. Preliminary risk assessments that have been done by EPA have used the same data as the Cal-EPA risk assessment, with similar results. If this exposure level were used to regulate the quantity of sand particles to which the members of the House of Representatives could be exposed during a floor debate on this bill, only a few sand grains would be allowed in the entire House Chamber!

Very high silica exposures found only in certain occupational settings have been limited by regulation over time. This has greatly reduced the incidence of a pulmonary condition called silicosis among workers. But there is virtually no known case of silicosis, a non-cancer illness, or lung cancer, from environmental exposures to sand particles. Does it make sense to create public fears about, and spend regulatory resources on, substances which the evidence shows pose spectacularly low risks to citizens?

**Small Business and Competitiveness: The High Opportunity Costs of Misplaced Emphasis**

Many regulations impede the ability of small business to compete in the emerging global economy. In my own industry, there are numerous obstacles to competitiveness that are perhaps unnecessary from a risk perspective. I would highlight two that are relevant to just one of the raw materials used in the metalcasting industry — again, sand.

**Regulatory impediments to the reuse of materials that are "cleaner than dirt."** Every year, foundries use more than 100 million tons of sand in the metalcasting process, and dispose between 7 to 8 million tons of this material. Approximately 90-95 percent of used foundry sand is not toxic when tested by the toxicity characteristic leaching procedure (TCLP) used to determine toxicity under the federal Resource Conservation and Recovery Act (RCRA). That portion of the used sand universe that fails to pass the TCLP test is easily identifiable by a specific production process that is its source. A recent independent study in Wisconsin showed used foundry sand to be less of a threat to the environment or human health than even natural background soils.

This material is, in fact, a commodity that can be made available for reuse in numerous construction-related applications. Technology also currently exists to convert used foundry sand into glass for use in roofing and other materials. Yet foundries across the nation face tremendous hurdles in getting approval for beneficial reuses of this byproduct of their process, so foundries end up paying ever-increasing disposal costs for sand.

The burdens imposed by these restrictions amount to a significant opportunity cost for small facilities. Instead of building in incentives to our regulations that allow small metalcasters to make comparatively more productive investments, restrictions are imposed on both reuse as well as disposal. Disposal costs for these and other reusable materials approach \$500 million for the industry — depending on landfill tonnage fees. This is too much to pay for materials which have been judged to be "cleaner than dirt."

We worked with Congress during the last effort to reauthorize the Resource Conservation and Recovery Act (RCRA) three years ago in order to make progress on beneficial reuse of foundry sand in a wide range of applications. Yet even as we sought to bring common-sense solutions to the debate, new industrial waste provisions were proposed that would have imposed new, additional costs on the industry's use of a critical raw material.

**The definition of solid waste: novel EPA interpretations of current RCRA regulations impede small-business production and are not risk-based.** Another key example of the problem of misplaced emphasis in regulation, and the potentially high costs that dampen competitiveness for small business, is found in the way EPA defines and regulates materials it considers to be solid wastes under the federal RCRA. The problems in the agency's definition of solid waste are manifold and well-known, and have had extremely harsh consequences for small businesses in various segments of industry.

The metalcasting industry has just recently been informed by regional EPA officials that the industry's onsite reuse of sand in the mold-making process is essentially considered waste recycling on which the agency believes it can impose a new set of regulations. Even in our heavily regulated operations, the agency has never before targeted this component of the industry's production process, whereby a foundry can reuse its sand numerous times for molds to make castings in continuous, on-site production. Many in industry believe EPA is venturing well outside its statutory authority in an attempt to regulate such recycling.

Reuse of this material is economical, poses no new risks to employees or the public, saves millions of tons of landfill space every year, and prevents millions of new tons of virgin sand from being extracted from the earth. The industry is scratching its head and asking, literally, "why is this happening?"

EPA has yet to clarify for the industry what is encompassed in its new interpretation of the definition of solid waste as it applies to this extremely low-risk, conventional practice which has never been secret or hidden from the view of regulators. We are totally opposed to this new

agency effort and are currently demonstrating to EPA why this process is a wholly inappropriate target, but we have thus far not made significant headway.

The time, resources, and effort spent by the industry and EPA on this problem could be devoted to some far more dangerous threat to the public or environment with much more promising opportunities for risk reduction. This truly is a supreme case of misplaced emphasis in regulation.

### **Conclusion: The Moral Imperative for Allocating Risk Resources Efficiently**

In a recent survey of the metalcasting industry<sup>1</sup>, environmental costs outranked all other categories of new capital expenditures faced by metalcasters. But the burden goes far beyond the direct costs of compliance. In my industry and others, small businesses cannot afford to have full- or even part-time environmental staff in-house, and face escalating costs of consultants and attorneys just to comprehend their obligations under the numerous statutes and numerous regulations.

Faced with these and other unique challenges, the small business community urges the 104th Congress to enact the provisions outlined in this legislation.

Improving the use of risk assessment, and making data and assumptions in risk assessment more transparent, will produce well-informed decisionmaking and build the confidence of the public that the most serious problems are being addressed. Further, strengthening the role of cost-benefit analysis in regulation will yield a better picture of the critical incremental costs of more protection.

And lastly, I believe that expanding the role of peer review will lend more credibility to assessments of our health and environmental challenges. All of these things are vital to win back the confidence of small business in a regulatory system that now suffers from a serious credibility gap.

Title III is a pragmatic and measured attempt to correct real flaws in our system without giving up the protection the public wants. I for one do not want to poison my workers or neighbors, or destroy the beauty of my community. I have no interest in paralyzing our regulatory system with hurdles and delays. But we need a departure from the status quo because small business in this country can no longer afford the tremendous economic costs of distorted priorities.

Contrary to those who maintain that it is immoral to focus on efficiency at the expense of human life, and that no life is too expensive to save, those in the small business community would respond that we have a moral obligation to be honest about the human condition and scarcity. We have a moral obligation to face up to the trade-offs that are part of living in this world and that are necessary in an era of scarce resources. It is true that life is precious, and for this reason we have no business wasting our valuable efforts and energies on foolish choices.

The need for risk-based decisionmaking is clear. Federal, state, and local governments continue to invest billions of taxpayer dollars in the regulatory process to protect human health, safety, and our environment. Our country needs a means to choose regulatory priorities, just as a small business or a family must prioritize its expenditures. The nation's limited financial resources should be utilized where they will do the most good and provide the most efficient protection for employees and citizens.

Enactment of Title III of the Job Creation and Wage Enhancement Act of 1995 would be an important step in the effort to modernize federal regulatory procedures and would allow the nation to focus its resources on real risk reduction. Ultimately, reasonable people of good will can disagree on the details, but the overarching and powerful concepts of this legislation must be given a try.

<sup>1</sup> December, 1993 issue; Foundry Management & Technology

The CHAIRMAN. We will move now to questioning, and I will recognize first the ranking minority member, Mr. Brown.

Mr. BROWN. Thank you very much, Mr. Chairman.

I sense a thread of agreement on the need to bring a little more common sense into the regulatory structure here, and I appreciate that very much. I also appreciate some of the examples that have been given of regulatory actions which do not appear to have a very good basis.

However, I am disturbed by an example referred to by two of the witnesses having to do with the CAFE standards and the failure to project a cost analysis or cost-benefit analysis that would reflect the number of motorists killed or injured each year due to the CAFE standards, and this illustrates several points, and I want to comment on it therefore.

First of all, these are not regulations, this is incorporated in a law passed by Congress in a Republican administration in 1975. The CAFE standards, 27.5 miles per gallon, were set in the law and they can't be changed by regulation of the agencies.

Now what the need for an estimate of the number of deaths could be without a corresponding estimate of the benefits I am not exactly sure, and this is a point that I wish to make. We could probably make some estimates of the number of deaths, but it would involve analyzing every accident to see whether it was due to a car that was 1,000 pounds lighter as a result of the CAFE standards, having to meet the CAFE standards, or if it was due to a drunk truck driver hitting an automobile and it would have killed somebody regardless of the CAFE standards, and I cite that as an example of the difficulty of coming up with meaningful figures.

I would also cite as a part of the difficulty of reaching any reasonable cost estimates the fact that the CAFE standards were put in primarily, as you indicated, Mr. Graham, for energy conservation reasons. Energy conservation has major impacts on both the effectiveness or the efficiency of our overall economy, and it has considerable side effects with regard to reducing our reliance on imported oil, which is a national security issue.

Now I would suggest to you that weighing these benefits might cause considerable difficulty for the normal bureaucrat in a risk assessment office in the National Highway Safety Bureau or whatever agency would be making it.

I am not citing this to criticize your criticism of the CAFE standards. I have been aware of criticisms of these standards for a generation. On the other hand, I have fought for reasonable regulation of this for more than a generation, but I would appreciate your commenting on the points that I have raised here, particularly as it affects a piece of legislation which deals with the regulatory process by administrative agencies.

Mr. GRAHAM. It is an excellent question and I think a good line of thinking for this hearing to reflect upon. I think if you look at the history of the CAFE program you have an example of the—of one of the problems in the behavior of regulators and legislators that I think we should talk about.

There was, I think, a clear focus on a target risk, a risk to the environment from excessive energy consumption, a risk to national

security from importing too much oil from the Middle East, and hence there was this sense, we have got to do something about this problem, we are going to do it by saying all new cars have to ultimately, or the fleet-wide average of new cars has to meet 28 miles per gallon, and the Government agencies went off and did their best to respond to that mandate.

In the process of doing that, we never had a full disclosure requirement that the Government ought to also tell the legislatures and the American people what are the risks and costs associated with the course of action that we have taken, and I think it is very important that the Government does follow the desire to try to conquer some of these serious problems in energy and the environment, but I think it is also very important that along the way they occasionally remind you, you know, what costs we are paying and what the risks are, because it may be along the way that we can find some smarter ways to conserve energy that don't actually involve making cars 1,000 pounds lighter, and I think that is really where the issue is, can we find some ways to save some energy and save lives at the same time rather than have to pit the two against each other.

Mr. BROWN. You mentioned the fact that there would be additional lives lost as a result of the standards. Have you not thought about or don't you think there should be considered the lives saved as a result of the improvement in health of the American people? And I cite this for a very personal reasons. I was elected to Congress in Southern California on a promise to clean up the air 34 years ago. I still haven't succeeded, and the leading supporters of action, including abolishing cars, are doctors whose patients die from lung cancer or other reasons of that sort, and there are quite a large number of those in Southern California.

Mr. GRAHAM. It is a good point, but a quick follow-up. If you think of the debate this country is having over electric cars right now, for example, I have never seen a good risk analysis that looks not only at the benefits of electric cars—and there are numerous benefits to having those types of cars—but what, for example, are the safety risks and the pollutant risks back at the power station of electric cars, and actually puts both of those on the table at the same time. This is the kind of risk analysis I am talking about.

Mr. BROWN. Well, I think we are in agreement on this need for additional information. The thrust of my questions is, first, we do have to distinguish between the Congress being at fault plus those irresponsible regulators, and we also have to recognize the complexity of the cost-benefit equation.

The CHAIRMAN. The time of the gentleman has expired.

Mr. Kazman.

Mr. KAZMAN. If I could just comment on your question, I was the attorney involved in the litigating of the CAFE case. The issue here was not Congress's failure to do a risk assessment but NHTSA's. NHTSA had lowered the standard, and it then made an administrative decision to let it become more stringent. NHTSA did not claim that this issue was too difficult to do, it claimed, and it still claims, that CAFE simply does not kill anyone, and that I believe and the Federal court agreed is demonstrably false.

You might recall when President Bush sent troops to the Persian Gulf some people accused him of running a blood-for-oil war, spilling American blood for gasoline. I do not believe that charge was correct, but it should be remembered, he made it clear that he was putting American lives at risk, he was sending troops into battle, not to Disney World.

NHTSA, in a sense, is also conducting a blood-for-oil war, as Mr. Graham's peer review published analysis makes clear, and, as a host of other research makes clear, CAFE kills people. NHTSA, however, is in the position of refusing not only to give us a casualty count but refusing to admit there is even a battle going on, and that, I believe, is fundamentally unfair. Whether you believe CAFE accomplishes good purposes or not, you can't evaluate it unless you really know what its cost is.

Mr. BROWN. Would you agree on the need of getting a figure on the number of lives saved also?

Mr. KAZMAN. Yes, and I have seen estimates of that, but I have never seen from any Government agency an estimate of what CAFE causes in terms of casualties.

Mr. BROWN. I apologize, Mr. Chairman.

The CHAIRMAN. Okay.

Ms. McCarthy.

Ms. MCCARTHY. Thank you, Mr. Chairman.

Mr. Garner, I wanted to visit with you a little bit and first of all to say what a treat it is to have you here as a local elected official today telling us your story from your experiences. I am very impressed with the Kentucky Outlook 2000 that you have provided to the committee members too. It shows that your State is looking into the future already on this important issue.

I appreciated your remarks too on judicial review and this question of certainty and how we arrive at that with a central estimate, but what I really wanted to have you discuss with me this morning was tell me how this legislation would actually make your life better, that of you and your Metropolitan Sewer District, because Mr. Brown just mentioned that perhaps the real source of many of the problems experienced at the State and local level are indeed the laws that Congress has passed. So would you reflect with me a moment about how this new Act would indeed make it better.

Mr. GARNER. Well, the best example I can give relates to the responsibilities that MSD has under the Clean Water Act to do a pretreatment program. We have in our community about 150 permitted industries that we regulate. These industries are subject to either categorical standards that are established by EPA and applied nationwide or to local standards that are developed to meet the local situation, but they are developed under a sort of very narrow set of rules that you have to follow.

What has happened as the program has evolved—and I have been involved with it from the very beginning—is that the emphasis has gone from dealing with problems that are demonstrable in the receiving water—in the streams, lakes, and rivers—to problems that exist in the computer. We do these hypothetical computer analyses of what might happen under worst case scenarios, and that is how we come up with the numbers that we are using.

I think that the foundation for doing that is pretty weak, and the rebuttal that either an industry or a local government who might challenge the way that the rules are set up can approach disagreement is basically zero or none. So if you have a credible basis for saying that, well, we put this into the computer and it really came out with a bad number, we really don't have a good mechanism for going back to our State or EPA agency, whichever one has the oversight responsibilities, and challenging the number, being able to demonstrate that it is a bad number and show the reasons why in the particular case it might be a bad number, and we are dealing with these things every day. I mean we are dealing with industries that are having to meet permit standards and permit limits that really do not necessarily reflect a real threat to the environment. So that would be one example.

Ms. MCCARTHY. Is it your feeling that the peer review process would address this—

Mr. GARNER. Yes.

Ms. MCCARTHY.—or what in this particular Act—

Mr. GARNER. Because those standards historically have not been developed where there has been an adequate amount of involvement from State and local government, or industry for that matter.

Ms. MCCARTHY. Let me explore with you further on how this would benefit you and what you do, the cost to the taxpayer, because that is something I raised in my initial statement and it is of concern to me.

I was a fiscal chairman in the Missouri House of Representatives, and bills that we studied were accompanied by fiscal notes, and they told us how much new FTE, for example, would be required for judicial proceedings for carrying out something such as a peer review. I suspect you are very close to the taxpayers in your role and probably hear from them with great frequency. I wonder how you see this new measure affecting them. We have heard some comments this morning about hidden costs. I haven't heard anything about cost savings, but I would really like your sense of what this new Federal Act would do.

Mr. GARNER. Well, to me what it will do is, it will at least put a more rigorous means test for evaluating legislation. Congress may choose to ignore the information and make a decision for other reasons, national security or whatever, but if there is good information on the table, at least legislation or regulations which come down the pike that have a weak foundation might be challenged before they become implemented.

I think that is all most of us really want. We are not against reasonable regulations or environmental laws that really protect the environment, but what we are seeing and experiencing are a lot of laws and regulations that really do not deal with environmental protection in a meaningful way and we are spending money on the wrong things.

Ms. MCCARTHY. What do you think would be the impact on the taxpayers in your community?

Mr. GARNER. Lower rates for their sewers.

Ms. MCCARTHY. How do you envision the Federal Government paying for title III, since we are imposing some new duties, for example, on rule-making and risk assessment, peer review, national

peer review, selective peer reviews on different topics? Where do you see these monies coming from?

Mr. GARNER. That is not my problem.

[Laughter.]

Ms. MCCARTHY. It is the guy behind the tree.

Mr. GARNER. But I think the issue more to me is that if a Federal agency, whether it is EPA or some other Federal agency, comes forward with a legislative recommendation and they can't tell you what it is going to cost, who it is going to affect, and what the benefits are from the legislation, then you ought not to be considering it. To me, that is pretty basic stuff. Our State legislature operates that way. I mean we don't dare put forward an environmental—proposed environmental law in our State without having a fairly rigorous analysis of what it is going to do, and what it is going to cost, and who it is going to affect. So I think that that burden for Federal agencies, it just makes common sense.

Ms. MCCARTHY. Thank you, Mr. Chairman.

The CHAIRMAN. The time of the gentlelady has expired.

Mr. Weldon of Florida.

Mr. WELDON. The question I wanted to ask was regarding the issue of asbestos removal. That is a subject of interest to me as a physician because I am aware of the cancer risk associated with asbestos, but people who come down with cancer-related or asbestos-related cancers are usually people associated with fairly high levels of exposure over a period of several years.

The amounts of asbestos in the environment in some of the buildings that we are being asked to remove the asbestos from is really microscopic, if not nondetectable, and actually removing the asbestos amounts to a fair amount of environmental risk for the individuals having to do it, and I am just curious if there was any risk assessment played in the decision regarding asbestos removal, if any of you are able to comment on that and if there was any comparative or substitute risk factor in that process.

Mr. GRAHAM. I don't know the specifics of EPA's analysis on that question, but I do know that the agency itself started with a fairly ambitious idea of all the asbestos that was going to be removed in a lot of schools, and I think when they faced the reality of what was really entailed in that type of task they have moderated considerably.

But one point I would note as it relates to this legislation is, H.R. 6 has an explicit requirement that the risks induced by a protective action or a protective regulation such as a substitution risk or a risk to workers who have to engage in the effort to take this asbestos out, that would have to be quantified and identified to the extent possible by any regulatory agency covered by H.R. 6.

So I think the question you are asking is a good one. It is also illustrative of the previous conversation on the safety risk of making cars more fuel efficient, and what this legislation requires is that Congress and the American people be told the truth about not just the risks that are going to be conquered but any risks that are going to be created, and I think that is a pretty minimum standard that we ought to apply to any kind of legislative regulatory program.

Mr. WELDON. Well, in follow-up to that, I wanted to ask if any of you think that the public really understands what we are talking about in this discussion of risk assessment and cost-benefit analysis.

The public gets very motivated when special interest groups talk about things like asbestos causing cancer, and the public will support very expensive efforts on the part of municipalities to remove asbestos from schools, but what we are talking about here is—I think it is a little bit harder to get the point across to the public, is what I am getting at. It is easy perhaps for all of us to understand, but it is a little bit arcane.

Mr. JASINOWSKI. Well, I think that you are right. I was saying to one of my colleagues that, having taught this in a university, I didn't really think we would have a full-fledged hearing on all aspects of this, so certainly it is quite technical.

I do think the public understands a couple of things though that they didn't a few years ago, and so there is a big change going on. One, they are beginning to get a sense of how much resources we are wasting in this area. The costs are not just the tax dollars paid for people to run it, the costs also are the extent to which we harm jobs and affect the economy and the costs of lost opportunities.

People are beginning to get a sense that there's an awful lot of resources going in here, because they are now starting to hear stories on the other side, and you have heard some of them today, and there are communities in Colorado and elsewhere where people are saying enough is enough, we have gone too far on the risk prevention side when the risks are small because of a lot of resources being used. I think they are beginning to get an economic sense of what is going on, and I think that that shows up in some of our polls.

Having said that, I think there is a long way to go before all the technical aspects are understood.

Mr. WELDON. Go ahead.

Mr. KAZMAN. I would like to mention, in the asbestos case that we discussed, EPA did do a cost-benefit assessment. The court found it so riddled with holes and statistical invalidities that it essentially threw it out.

But one place where EPA did start on this whole asbestos campaign was with industrial concentrations that were 4,000 times the level of the asbestos found in the normal public building, and they once again did an extrapolation from that.

Yes, when the public hears there is a deadly cancer-causing chemical substance present in our homes and our public buildings and our schools, they get very scared. If, however, agencies were to tell them in the same breath, "And it is almost as deadly as a toothpick," that would go quite a bit toward calming them down.

Mr. GRAHAM. Just a quick addition. This is what Justice Breyer calls the vicious circle. The public is concerned about the health and safety of their families. The Government performs a worst case risk assessment, says even a single fiber of this asbestos could conceivably cause cancer. The Government says that to its citizens. That gets the citizens even more concerned. They mobilize to move. He is talking about that as the vicious circle that leads to the spending problems. The problem for our economy that you just

heard about, the solution has to come from Government. Congress has to step back and say we do not want worst case estimates of risk driving this vicious circle, we want realistic estimates of risk based on the best available science, and I think that is what H.R. 6 tries to do, and I think it is a very constructive effort.

Mr. WELDON. Thank you.

The CHAIRMAN. Thank you, Mr. Weldon.

Mr. Barcia.

Mr. BARCIA. Thank you, Mr. Chairman.

I have one question for Mr. Holman.

Scott, the example used and highlighted in your submitted testimony to illustrate potential savings to industry cites the costs incurred by foundries who must dispose of some 7 to 8 million tons of sand each year at an industry cost of roughly \$500 million depending on local landfill tonnage fees, and I can say I appreciate that as a former four-year employee of the Nodular Iron Castings Foundry in Saginaw while I was a student at Saginaw Valley State University and have some personal experience with that sand and the amount that is used by the foundry industry.

You also note the varied uses or reuses for foundry sand and the subsequent regulatory hurdles for getting approval for reuse of the foundry sand. My question is similarly specific. How would this risk assessment legislation allow for faster, easier reuse of this material found, as you note, to be less of a threat to the environment or human health than natural background soils?

Mr. HOLMAN. You have been through my plant, and you know how we use sand, and we use a lot of it. This is beach sand. That is something that is pretty innocuous. Depending on the material that you cast in it—we cast steel and so forth—and the binders that you use to hold it together, this sand can be more or less in need of being disposed of at a landfill or under construction sites. In most cases—and I am talking about 90 percent—this can be used in a very beneficial way.

My own example is that it took us over three years of multiple testing to finally get the DNR to obliquely say that it could be used for landfill cover in the landfill and therefore a resource because the landfill was buying sand to do the daily cover. Now they are using our sand in daily cover at the landfill.

But there are problems with that as well, and that is that we are consuming landfill space, which is expensive, where it could be possibly used for construction fill, used in concrete use and other materials. But if this process of risk analysis had been done on it, perhaps we would have discovered that most of it has a very low—carries a very low risk and therefore we would not have had to go through the arduous and lengthy testing process and without any promise of results of being able to use it any place.

We feel that much of our sand could be used outside of the landfill and save that space, and I think this process would have helped.

Mr. BARCIA. Thank you for your response.

Mr. Chairman, just one final observation. A few years ago when I was in the Michigan State Legislature we had a similar situation that was basically involving the use of fly ash, and I know, Mr. Holman, that you are familiar with our local cement producing

plants in the Bay County area. One of the by-products is an inert substance known as fly ash, and at one point our Michigan Department of Natural Resources and the Environmental Protection Agency considered this as a hazardous substance, and subsequent to our involvement where we basically—there were some hearings held both at the State level and at the Federal level here in Congress when it was determined that fly ash was basically an inert compound that didn't represent a threat to the environment, and previous to that time it was being landfilled at a tremendous cost to cement producers and others, and electric producers, that in fact now it is being used in construction, the construction of State buildings, State highways, and it is now a useful by-product of the manufacturing process.

So hopefully something can be done to alleviate the tremendous burdens, some regulations on the costs associated with disposal of a very necessary by-product to your manufacturing process.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Barcia.

Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman.

I want to thank the gentlemen for testifying and for citing specific examples to elucidate their testimony. I have a few questions that pertain to actually the wording and definition within this bill before us.

For instance, in title III there seems to be like a less than clear criterion for the regulations that this would apply to. A major rule is defined as one which has an economic impact of \$25 million or more, causes a major increase in costs or prices, or has a significant effect on competition, employment, investment, productivity, innovation, or the ability of U.S. firms to compete internationally. I have three kind of questions pertaining to that. I don't know whether you can answer them or not. For instance, what percentage of existing environmental regulations do you think would be covered by this definition? If anyone would like to comment on that.

Mr. JASINOWSKI. I don't know the answer to what percentage. I think that you ask a question which is central to making this process more efficient, and I think there is room for debate about whether or not "major" should be defined a little more broadly.

Our own view in the coalition is that you might move the threshold up to a \$50 million regulatory cost, and I don't think there is anything magic about our number or the number in the bill, I just wanted to confirm that you raise a question, I think it is very central. I think that probably the best way to deal with it is on the size of the cost as a basic threshold, and I think then you would find that the percentages were substantially reduced.

The CHAIRMAN. If the gentlelady would yield for just a moment.

Mrs. MORELLA. Yes, indeed.

The CHAIRMAN. We have asked CRS to look into that question. I am told that they have given us some material on that, and we will be very happy to share it.

Mrs. MORELLA. Good, and we will probably have it before—maybe before hearing number two comes up on this.

The CHAIRMAN. We can certainly make that available to you.

Mrs. MORELLA. Thank you.

Again pertaining to the major rule definition, you wonder how many new Federal employees you might need. That is another question I think this committee will be considering, to implement the envisaged risk assessment for those rules, and I also wonder about whether or not disagreements would be subject to litigation. Do you see this as a problem?

Mr. JASINOWSKI. I will just make one brief comment, because it is a point of disagreement with your premise that more employees are going to be needed.

I tried to indicate in my opening remarks that I think a restructuring of the way we currently do regulatory and health policy—which I think has a lot of people not doing useful things, and that if the private sector can reduce its costs by 20 percent over the last decade we can reduce the number of people in many of those areas—I don't think we ought to look at this as something which increased Government costs or increases the number of employees on a net basis. We may have to put some more people in risk assessment and cost-benefit analysis, but there are plenty of other areas where we can reduce that. I don't think we would support a substantial increase in employees or funds to do this.

Mrs. MORELLA. Yes?

Mr. GARNER. I would encourage you to consider a higher limit as a practical matter. Twenty-five million dollars in terms of impact of a Federal law or regulation is almost nil, and I just think from a paperwork point of view that a higher threshold would make more sense.

Mrs. MORELLA. And I guess you would agree that we have a concern about litigation that could ensue from definition of the major rule?

Anyone want to comment on that?

Mr. GARNER. Well, I think you want to avoid, and as I said in my testimony, I think you want to avoid setting this up so that it becomes the subject of judicial process. We already have enough of that. I don't think it would contribute anything from a meritorious point of view. I am sure others on the panel probably disagree with that.

Mr. JASINOWSKI. Well, I think that the same principle that applies with respect to the threshold question—that is to say, we don't want to apply this to every regulatory action across the board, it would be wasteful—applies also in the litigation area, and, as we try to indicate in our testimony, we believe that judicial review appropriate but that it really needs to be targeted and justified with criteria that don't bog down the system. I do not think we want to apply judicial review in a helter-skelter way across everything, and I think that is a difficult area where we want to work with the committee to define what is the best way for us to target judicial review.

Mrs. MORELLA. Did you have a comment, Mr. Kazman?

Mr. KAZMAN. I have a quick comment. The first point is that one thing to keep in mind is that wherever you set this threshold you create an incentive for agencies to redefine rules, to divide rules up in such a way that they get under the threshold, so there is going

to be a lot of gaming on whatever you do, and I hope you will think that through when you do it.

One implication that I have from that is that at some point we are just going to have to trust the regulatory agency to actually tailor the amount of analysis they do to how important the rule is, and if Congress would actually explicitly authorize the agencies to say we are going to do a smaller analysis on a less costly rule but have a more in-depth analysis on a more costly rule, and I would say the same thing might apply on the public health and environmental protection side.

So I would support a more narrative position that says you shall always do this kind of analysis but you can have a small analysis for a small problem and a big analysis for a big problem, because any threshold you set, I think you set in motion some pretty bizarre behaviors.

The CHAIRMAN. The time of the gentlelady has expired.

Mr. Ehlers.

Mr. EHLERS. Thank you, Mr. Chairman.

I have a few observations to make, and I invite the panel to respond to them.

I am concerned a little bit about everyone assuming that risk analysis is going to solve all our problems, and I don't want my comments to think that I am opposed to risk analysis. We have to do it, we should do it, and we will do it, but too many people I have encountered in the past year think it is going to be the panacea that is going to solve our problems.

As Dr. Graham observed, we can only deal with our best available science, and the little interchange we had here earlier about CAFE standards illustrates the problems. If you really want to analyze that, you also have to factor in the greenhouse effect and the problems that is going to create. Using best available science, you are not going to get very definitive answers with regard to that component, and even the EPA assessment on asbestos dangers—the first assessments were done with best available science, and there may have been some questionable things—certainly didn't do a risk analysis, but it looked like there was a serious problem. Further study revealed that it was not that serious.

So I want to, I guess, partly as my role—in my role as a scientist here say don't expect miracles out of this process, it is going to be an improvement, but let's recognize its limitations.

That leads to the point I want to make. I think we have to be very careful in this bill, Mr. Chairman, to try to somehow limit judicial review of the risk assessment because it is not at all hard to tear apart a risk assessment and argue minute scientific points which you simply can't establish because they are, in the words of Alvin Weinberg, who was former director of Oak Ridge Laboratories—they are really transscientific; they sound scientific, they have a scientific basis, but you can't answer the question because you can't do the experiments for several more years.

So I would advocate trying to establish a judicial review mechanism that really tries to limit the opportunities to tie this up in court endlessly dealing with aspects of the risk analysis.

The final observation is one that has been raised already about educating the public. I have found through my years in this busi-

ness that is a virtual impossibility, because they tend to look at this in terms of absolutes, not in terms of relative risk, and to really make informed judgments we in the Congress and those in the bureaucracy have to make relative risk decisions and decide whether it is worth \$100 million to save two lives in one particular area or whether it is worth \$50 million to save 20 lives in a different area, and unfortunately these issues are generally presented to the republic as, we are making a coldhearted decision to have people lose lives, and that is not the case. We have to make a relative risk decision.

The public does that too, incidentally, and they have done it through the issues they think are important and which they register at the ballot box in one way or another, and so they happen to think that nuclear power is extremely dangerous, and so they are willing to spend billions of dollars regulating it to save one life whereas they don't think cars are all that dangerous and so we don't spend that much time or money regulating cars and driver behavior.

Mr. BROWN. Would the gentleman yield to me?

Mr. EHLERS. I am finished with my statement, and I will be happy to yield, yes.

Mr. BROWN. I want to compliment the gentlemen on his statement. It certainly reflects the common sense point of view that I think we would like to have incorporated in our regulations, and I am depending upon him to continue to advance the kind of point of view that he has just advanced here. And while you have yielded me time, may I ask unanimous consent to include in the record a study on the effect of car size on fatality and injury risk prepared by the National Highway Traffic Safety Agency in July of 1991 and a table showing motor vehicle deaths and rates and the fact that since the CAFE standards went into effect the deaths per 10,000 motor vehicles has decreased by 37.5 percent, the deaths per 100 million vehicle miles has decreased by 46 percent, and the deaths per 100,000 population have decreased by 29.1 percent.

The CHAIRMAN. Without objection.

[The documents follow:]

## EFFECT OF CAR SIZE ON FATALITY AND INJURY RISK

Overview

In recent years, as cars have been reduced in size and weight relative to vehicles produced before the early 1970's, there has been a heightened interest in determining the effects of these changes on motor vehicle safety. To address these questions, the National Highway Traffic Safety Administration studied the effect of changes in car size on fatalities and injuries to car occupants in rollover crashes, two-car crashes, and collisions of cars with trucks and fixed objects. After a general overview of the effects of car size, each of the individual studies is reviewed and discussed. While the agency has completed key analyses as of April 1991, it will continue to study the problem as additional data become available.

Effect of Car Size

During model years 1970-82, passenger cars became substantially smaller in the United States. The median curb weight of new cars involved in fatal crashes decreased by about 1000 pounds (from 3700 to 2700 pounds), the wheelbase by about 10 inches, and the track width by 2 or 3 inches. The size reductions of the 1970-82 period were the result of a market shift from full-sized cars to subcompact and imported cars and, after 1975, downsizing within many domestic car lines. Since 1982, the average size of new cars has remained rather stable. The average size of the entire automobile fleet, however, continued to decrease throughout the 1980's as pre-1975 cars were gradually retired and replaced with new cars - and it is only now approaching 2700 pounds.

Based on studies completed as of April 1991, NHTSA estimates that a reduction of the average weight of new cars from 3700 to 2700 pounds (or the associated reductions in car length and width) resulted in increases of nearly 2,000 fatalities and 20,000 serious injuries per year.

Car size has a much larger effect on fatality risk in rollover crashes than in other crash modes - not because small cars are less crashworthy in rollovers, but because they are more rollover prone. Narrower, lighter, shorter cars tip over more easily than wide, heavy, long ones under the same crash conditions. The analysis methods do not identify which individual vehicle size parameter (track width, curb weight, wheelbase, etc.) is the principal "cause" of this added rollover proneness. Nevertheless, the analyses show that about two-thirds of the increase in fatalities occurs in rollover crashes.

Analyses also show that small cars are less crashworthy than large cars. For example, small cars may offer inferior protection against intrusion by fixed objects into the passenger compartment. The larger expanse of structure in full-sized cars may help cushion the occupant against

deceleration forces. The 1000 pound weight reduction is associated with increases of about 10 percent in fatalities and serious injuries in single-vehicle nonrollover crashes.

In a collision between two cars, it is well known that the occupants of the lighter car fare much worse than the people in the larger car. The smaller the car, the greater the vulnerability to injury, but this added risk is at least partially compensated by the fact that small cars are less able to inflict injuries on the occupants of other vehicles. For this reason, a few safety experts have argued that fleetwide reductions in car size would not increase serious injuries in two-car collisions. NHTSA's analysis, however, reveals that a collision between two small cars is more likely to result in serious injuries than a similar collision between two large cars, by almost 10 percent for a 1000 pound weight reduction.

The findings from the accident data - that small cars are inherently less safe than large cars - are supported by an analysis of crash test data from the agency's New Car Assessment Program (NCAP). In that program, the agency provides information to consumers on the relative frontal protection offered to occupants in a 35 mph barrier crash. The test can be likened to two similar vehicles striking each other head-on, each traveling 35 mph (70 mph closing speed) or the vehicle striking an immovable object, such as a bridge abutment, at 35 mph.

From an analysis of 250 crash tests, the agency concludes that small, light vehicles expose the occupants to more danger than large, heavy cars. This occurs because crash forces are imposed on the small car occupants quickly and in a concentrated manner, while occupants of large cars experience a more gradual deceleration. The forces result in the occupants of small cars contacting interior components at higher velocities than do those in larger vehicles, with a greater potential for injury or death.

#### Relationship of Safety to Fuel Economy Rulemaking

While some hint that this is a "new" issue, raised solely to combat higher CAFE standards, the facts show that the Department of Transportation has long been concerned over the potential tradeoffs between fuel efficiency and safety and has voiced those concerns numerous times over the past 14 years. For example, in March 1977, as part of a Notice of Proposed Rulemaking to reinstate the automatic occupant protection standard, NHTSA stated that fuel economy standards were "expected to result in the reduction of the size and weight of many passenger cars (and) the lighter vehicle is less safe for its occupant, because less vehicle mass and crush distance are available to absorb crash forces. Improved vehicle structures are expected to compensate for reduction in weight and size to some degree, but it appears that the safety need for occupant protection may increase in the relatively near future (emphasis added)." In the final rule on this subject published in July 1977, the agency again stated that "the trend toward smaller cars to improve fuel economy...contains

potential for increased hazard to the vehicle's occupants." And, in the first ever fuel economy rule issued by the Department (June 30, 1977), the safety issue was again raised, with the statement that "reasonable conclusions can be made...that there will be a significant adverse safety impact [of fuel economy standards]" unless other measures are taken to counteract these effects.

In more recent fuel economy rulemakings (for example, the agency's October 1986 decision to amend the model years 1987 and 1988 passenger car fuel economy standards), the agency expressed concern that, while standards in the range of 26.0-27.5 mpg would not have adverse safety effects (because of the small range and the lack of leadtime for manufacturers to redesign their products), standards above 27.5 mpg could have a significant impact on safety if consumers were "forced" into smaller and lighter cars. In these rulemakings, the agency repeatedly stated that, if it were to consider setting standards above 27.5 mpg in the future, and if such standards would result in further weight reduction, adverse safety effects would occur. Major downsizing of vehicles would result in a tradeoff of lives and injuries for improved fuel economy.

#### Other Studies on the Relationship of Car Size to Safety

The Department is not alone in being concerned over the size and weight of vehicles and resultant effect on safety. During the past 12 years, numerous public and private groups have studied the relationship of car size to safety. The Office of Technology Assessment of the United States Congress, the National Safety Council, the Brookings Institution, the Insurance Institute for Highway Safety and the General Motors Research Laboratories all agreed that reductions in car size and weight pose a safety threat.

#### Effects of Regulations and Improved Traffic Safety

The agency and other safety specialists attempt to improve vehicle safety through a variety of programs. Occupants of vehicles of all sizes are benefiting from improvements in roadway and vehicle design, increased safety belt use, reduced alcohol involvement, state and local programs to improve highway safety, and other factors. These efforts to improve safety will continue. As a result of these efforts, fatalities per vehicle mile traveled, fatalities per registered vehicle, and fatalities per population continue to decline over time. The decrease in car weight (despite the association between car weight and safety in any one year) has not led to increases in the absolute annual number of fatalities, though it has led to fatality savings foregone by the shift to lighter cars. It is the continuing overall improvement in safety that has led many safety specialists to doubt that there actually is an association between car weight and safety.

One of the principal safety improvements has been the increase in safety belt use. NHTSA has found that safety belts are especially effective in

preventing occupant ejection in rollover crashes, where the majority of fatalities among unrestrained occupants involve ejection from the vehicle. Since reductions of car size increase fatalities in rollovers more than in all other crash modes combined, one of the best ways to combat the safety problem of smaller cars is to achieve continued increases of belt use.

#### National Academy of Sciences Study

To further address the issue of fuel economy and safety, in December 1990 the Department of Transportation announced that it would sponsor a study by the National Academy of Sciences (NAS) to determine the potential for improving fuel economy for new passenger cars and light trucks in the next decade, while still meeting environmental and safety needs. As Secretary of Transportation Samuel K. Skinner noted in announcing this study, "Our goal is to provide the American people with cars and light trucks that offer the best feasible combination of safety, fuel efficiency, and cleaner air."

The first phase of the study is scheduled to be completed in Summer 1991. It will result in estimates of fuel economy levels that are practical and achievable over the next decade, and will identify those technologies that could bring them about. It is also expected to identify any barriers to the rapid marketplace introduction of the suggested fuel-saving technologies. A second phase of the study, scheduled for completion by March 31, 1992, will expand upon the earlier findings, and consider other appropriate aspects of fuel economy.

Safety consequences are a key part of this study. Among the factors included in the study are the state of the art in the applications of technologies relevant to achieving higher fuel economy and improving safety, the likely effects of these technologies on vehicle safety, and a consideration of the impacts of heightened public concerns for safety. This study should shed additional light on potential trade-offs between fuel economy and safety in the future.

### Summaries of the Analyses

There are five principal types of crashes involving passenger cars; during 1987-89, annual counts of passenger car occupant fatalities in these crash modes, based on the Fatal Accident Reporting System (a census of fatal crashes), were approximately as follows:

o Rollover	4,500
o Single-vehicle nonrollover (e.g., impact with tree)	7,000
o Collision of two passenger cars	5,000
o Collision of car with light truck, van or utility veh.	4,500
o Collision of car with large truck	2,500

Each crash mode is analyzed separately because the influence of car size is different (crash-proneness, crashworthiness). Also, because of data limitations, the effect of car size on fatalities may be derived from a different data source or analysis method than its effect on serious injuries. That results in a matrix of individual analyses.

The Fatal Accident Reporting System contains records of hundreds of thousands of fatalities, but is used only for the analysis of rollovers: in nonrollovers the objective is to study fatality risk per 100 crash involved persons (crashworthiness) and that cannot be done with FARS, which is limited to fatal involvements. For nonrollovers, State accident files are more useful because they offer documentation of all passenger cars involved in reported crashes, whether the driver is injured or not. Individual large State files are excellent for studying the effect of car size on the risk of serious injuries, but the fatality sample from any one State is much more limited. Based on State data analyzed so far, statistically meaningful results have been obtained on fatalities in single-vehicle nonrollovers, but not yet on two-car crashes and collisions of cars with large trucks.

The analysis of collisions of cars with light trucks has been hampered by a lack of detailed information on the weights of light trucks. NHTSA will study that crash mode when such data become available.

The analyses of rollovers and injuries in single-vehicle nonrollovers have been previously published. The other statistical analyses are new material. Another analysis utilizes agency crash test data to evaluate the effect of weight on the risk of injury.

All of the analyses study the effect of historical changes in car size on injuries and fatalities. They describe what actually happened to cars in the 1970's and 1980's, as they changed in size and weight. The quantitative relationships between car size and injury or fatality risk that have applied in the past 20 years cannot necessarily be projected into the future, especially if the next generation of cars is substantially smaller than the mix on the roads today. Nevertheless, the agency believes the analyses are instructive in not only showing the safety effects of past downsizing but are also the direction of the safety effects which can be expected with future changes in vehicle size and weight.

## Motor-Vehicle Deaths and Rates, 1913-1993, Cont.

Year	No of Deaths	No of Vehicles (millions)	Vehicle Miles (billions)	No of Drivers (millions)	Death Rates		
					Per 10,000 Motor Vehicles	Per 100,000,000 Vehicle Miles	Per 100,000 Population
1913	1,111	1.00	1.1	1.1	1.1	3.1	22.5
1918	2,111	1.3	1.4	1.4	1.1	3.1	23.6
1920	5,152	1.59	1.6	1.6	3.3	3.50	23.8
1925	5,112	1.6	1.7	1.7	3.3	3.50	23.4
1930	5,135	1.6	1.7	1.7	3.3	3.30	22.4
1935	4,112	1.65	1.7	1.7	2.7	2.88	19.8
1940	4,452	1.67	1.7	1.7	2.7	2.68	19.0
1945	4,113	1.7	1.7	1.7	2.6	2.69	17.6
1950	4,113	1.7	1.7	1.7	2.5	2.53	19.3
1955	4,113	1.7	1.7	1.7	2.6	2.60	17.9
1960	4,113	1.8	1.8	1.8	2.6	2.51	19.9
1965	4,113	1.8	1.8	1.8	2.6	2.42	20.1
1970	4,113	1.8	1.8	1.8	2.4	2.26	19.3
1975	4,113	1.8	1.8	1.8	2.4	2.19	18.8
1980	4,113	1.8	1.8	1.8	2.6	2.00	17.3
1985	4,113	1.8	1.8	1.8	2.1	1.82	16.0
1990	4,113	1.8	1.8	1.8	2.1	1.83	16.3
1993	4,113	1.8	1.8	1.8	2.1	1.83	16.3
Changes							
1983 to 1993	- 6%	+16%	+38%	+14%	-19%	-32%	-14%
1992 to 1993	+ 3%	+ 1%	+ 2%	+ 2%	+ 1%	+ 1%	+ 2%

Source: Data from National Center for Human Statistics except 1964-1992 (revisions) and 1993 (preliminary). Death rates are based on data from state traffic authorities. Some technical adjustments have been made to the data. Vehicle registrations, mileage and drivers from Federal Highway Administration. \*Mileage rate not based prior to 1973.

## Vehicle Defects in Motor-Vehicle Accidents



According to the National Highway Traffic Safety Administration (NHTSA) General Estimates System, vehicle defects contributed to approximately 1.6 per cent of the police-reported motor-vehicle accidents in 1993. Of the accidents in which a defect was listed, over 32 per cent were due to a defective brake system. Another 29 per cent were due to defective tires.

NHTSA's Fatal Accident Reporting System listed approximately 8 per cent of fatal motor vehicle accidents in 1992 as attributed to one or more vehicle defects. Of the fatal accidents in which a vehicle defect was determined, over half (53.1 per cent) were the result of defective tires. Another 21 per cent were due to defective brakes. The remaining 26 per cent included defective headlights, steering systems, etc. The table below shows the per cent of vehicle defects listed in fatal and injury accidents.

Type of Defect	Fatal Accidents	All Accidents
Total	100.0%	100.0%
Tires	53.1	26.9
Brake system	24	32.1
Steering system	5	0
Other lights	5	5.3
Other defects	24	4.0
Other defects	22	1.1
Other defects	22	2.3
Other defects	11	0.4
Other defects	13	2.1
Other defects	5.9	2.1

Source: National Highway Traffic Safety Administration, "Fatal Accidents Involving Motor Vehicle Defects," NHTSA, 1993. \*Other defects include defective headlights, steering systems, and other defects. \*\*Other defects include defective headlights, steering systems, and other defects. \*\*\*Other defects include defective headlights, steering systems, and other defects.

## GOVERNMENT

# Myth That Environmental Regulations Cause Job Loss is Debunked

■ **Study reveals the number of layoffs and plant closures is actually small and that regulations have a small positive effect**

Conventional wisdom says that environmental regulations cost jobs. But a new study by the Washington, D.C.-based Economic Policy Institute says that conventional wisdom is wrong. Two decades of research into the relationship between jobs and environmental protection actually reveals that the number of layoffs and plant closures caused by regulations has been surprisingly small.

The main point of the study—and all economists agree—is that at the national level, there is no trade-off between jobs and environmental protection. At the local level, when you look at the data, actual layoffs that result from environmental and safety regulations have been quite small—on the order of 1,000 to 2,000 a year," says study author Eban B. Goodstein, an economics professor at Skidmore College, Saratoga Springs, N.Y.

In fact, Goodstein's research shows that the vast majority of economywide—or national-level—studies indicates that environmental regulation has a small positive effect on overall employment. This is so because environmental protection requires the intensive use of labor or domestically produced materials in such projects as recycling and construction of sewage facilities.

The jobs created by environmental regulation are heavily weighted to blue-collar sectors, not government- or private-service sectors. In 1991, 57% of jobs generated by environmental spending were in communications, manufacturing, transportation, and utilities; only 22% of all nonfarm jobs were in these

sectors. And despite the charge that environmental regulation only creates jobs for government bureaucrats, government jobs accounted for just 11% of environmentally related employment compared with 17% economywide.

Using Labor Department data from 1987 through 1990, Goodstein found that only four plants per year were shut down because of environmental or safety regulations. This translates to less than 0.1% of all large-scale layoffs.

As an example of how prediction overstates reality, Goodstein cites a 1990 study done by the Business Roundtable, a Washington, D.C.-based association of chief executive officers. That study attempted to predict job losses from regulations likely to be promulgated under the Clean Air Act of 1990.

During debate over renewal of the clean air law, many people expressed concern over the possible economic consequences of tendered amendments. Concern about potential job losses was so high that legislators eventually included a provision in the 1990 Clean Air Act amendments allocating \$50 million per year for job retraining funds.

The Business Roundtable study predicted that a minimum of 200,000 jobs and possibly as many as 1 million to 2 million jobs would be wiped out. "The reality," Goodstein tells C&EN, "is that as of June 1994 only 2,363 jobs had been lost because of Clean Air Act regulations."

Johanna Schneider, director of communications for the Business Roundtable, points out that the study's "predictions of job loss were based on the Clean Air

## Environmental protection is not key reason for mass layoffs

	1987		1988		1989		1990	
	Layoff events	Job loss	Layoff events	Job loss	Layoff events	Job loss	Layoff events	Job loss
Automation	9	951	7	737	11	1,378	11	1,688
Bankruptcy	43	7,259	76	16,559	81	18,599	100	26,428
Business ownership change	88	30,955	92	18,973	82	19,147	78	16,989
Contract completion	147	27,695	178	50,822	225	50,971	201	40,167
Domestic relocation	49	10,677	68	12,816	68	1,138	114	18,512
Environment related <sup>a</sup>	4	511	4	388	5	1,304	4	390
Import competition	40	8,328	34	8,222	43	8,310	69	10,028
Labor-management dispute	43	12,592	26	2,824	47	40,387	na	na
Material shortages	11	1,872	20	2,169	24	4,318	20	5,859
Model changeover	17	16,441	21	7,186	17	9,089	15	3,039
Overseas relocation	30	4,963	10	1,225	6	1,189	13	3,122
Seasonal work	516	101,168	710	144,522	889	175,970	884	167,287
Slack work	535	94,071	450	69,764	661	102,607	943	142,038
Other (including reorganization)	240	51,207	229	51,744	255	46,778	284	97,474
Not reported	162	23,826	276	45,764	210	53,604	168	24,704
TOTAL	2,020	406,887	2,322	450,300	2,764	572,570	3,078	586,690
ALL REASONS <sup>a</sup>								

a. Includes environmental and safety-related shutdowns. b. Employer reported. na = not available. Source: Department of Labor.

## GOVERNMENT

Act amendments as initially introduced, not as modified by Congress." And, she adds, "the Clean Air Act of 1990 has not yet been fully implemented."

At the local level, the personal and social costs of job loss and unemployment cannot be minimized, whether they are the result of environmental and safety regulations or more general causes, Goodstein says. But even at the local level, the trade-off between jobs and the environment "is shockingly small when you look at the data," he explains. In fact, more jobs are probably lost because of corporate downsizing, import competition, and defense cutbacks, he adds.

The trade-offs between jobs and environmental protection are most apparent in extractive industries such as mining and logging where local job loss and unemployment can be very significant. But even in these instances, new jobs dependent on a clean environment or providing substitute products for the "locked up" resource are generated elsewhere in the economy. Over time, job gains will generally balance job losses, "though national policy will have to address local problems of dislocation," the study states.

Nor has environmental protection been responsible for the decline of manufacturing jobs in the U.S. because companies have fled to "pollution havens"—countries where environmental regulation is lax. Companies are relocating to less industrialized countries, but primarily because labor costs are low, Goodstein says.

He advocates that immediate steps—

expanded job training and adjustment assistance—be taken to address job loss in manufacturing. In the long run, Goodstein contends, markets for clean manufacturing and energy technologies will provide the high-wage jolt to the economy that car manufacturing and defense provided in the 1950s and '60s.

"Demand for clean technologies will be the driving force behind industrial job creation," Goodstein says. "Ensuring that U.S. firms develop and maintain the lead in these fields will allow the country to capitalize on high-wage employment opportunities in environmental protection."

John C. Shanahan, environmental policy analyst with the Heritage Foundation, disagrees. "The idea that environmental regulation is good for the economy is absurd. What's ignored in the [Goodstein] study is that the dollars spent on environmental regulation—dollars that create jobs, technology, and exports—can't be spent where they would be most productive. The free market always gets more economic productivity and economic growth out of every dollar spent than the federal government does."

In short, Shanahan says, "What the study ignores is that whatever productivity is created by environmental regulation is far outweighed by economic activity lost elsewhere."

The Economic Policy Institute study, "Jobs & the Environment: The Myth of a National Trade-Off," can be obtained from Public Interest Publications by phoning (800) 537-9359; the price is \$12.

LOS ANGELES

it all happen exists, too. So does the marketing hype. But the council says the overall use of information technology faces all sorts of barriers that need to be overcome: costs, human resistance, incompatibility between systems, multitudinous legal hurdles, and privacy concerns.

Paul A. Allaire, chief executive officer of Xerox Corp., which helped generate the information revolution, remains optimistic. "As the National Information Infrastructure grows," he says, "it will have a revolutionary impact on national competitiveness. Those nations that establish this infrastructure and develop a broad range of applications first will have a tremendous competitive advantage over those that lag behind."

But the barriers do exist. Take education. "Schools and application developers both learned that unless NII applications are integrated into the regular curriculum, students cannot realize the full benefits of the new technology," states the report. "They miss the chance to work on projects with students from around the world and to tap into a wealth of reference sources worldwide. Indeed, students and teachers tend to lose interest in new technology quickly if it appears to be a gimmick rather than a real aid to learning."

The council points to some examples where schools successfully integrated technology with teaching. A key practice was establishing a mentoring program in which information-literate teachers personally trained colleagues more skittish about the new tools and techniques.

The report says the one overriding difficulty in establishing a fully operational NII is society's "basic resistance to change." Most organizations are more comfortable with the slowness and deliberateness of paperwork. People in business and the professions are uncomfortable with sharing their information, fearing loss of control of their domains. Few are convinced that the costs of installing the equipment and learning how to use it will outweigh the benefits. Also, extensive legal and regulatory barriers remain to be crossed. Physicians, for example, cannot practice electronically across state lines; their licenses are valid in only one state.

In addition, much of the technology businesses need to interact through remains incompatible. And organizations continue to resist because benefits and costs are difficult to measure. The report cites example after example of barriers and opportunities in manufacturing,

## Report notes information superhighway barriers

Republican House Speaker Newt Gingrich of Georgia has recently boosted the already high visibility of the information revolution in his fervent talks about computerized communications that will revolutionize tomorrow's politics. According to Gingrich and futurologist Alvin Toffler, this "third technological wave" (after agriculture and manufacturing technology) will revolutionize democracy, commerce, and everything else by putting everyone on-line with everyone else, empowering all.

Not so fast, says a recent report. Significant barriers need to be overcome before the miracles of information technology can come to fruition in schools, businesses, medical centers, and homes.

The report was issued late last month by the private, Washington, D.C.-based Council on Competitiveness. The council is a think tank established in 1981 and composed of about 150 leaders from high-tech corporations, universities, and other areas.

A council task force has been studying the so-called National Information Infrastructure (NII), also known as the information superhighway. Its latest report on the subject, "Breaking the Barriers to the National Information Infrastructure," is based on a conference the council sponsored last September.

As the report points out, the hardware that links information to users is there. The always evolving software that makes

## Talking Points on Environmental Costs

1/19/95

- "THE COST OF CLEAN" WAS A 1992 EPA REPORT THAT ESTIMATED ANNUAL (NOT CUMULATIVE) ENVIRONMENTAL CONTROL COSTS IN 1986 DOLLARS. IT ESTIMATED THAT ANNUAL POLLUTION CONTROL COSTS (NOT CUMULATIVE) WOULD GROW FROM \$88 BILLION IN 1988 TO \$160 BILLION IN 2000.

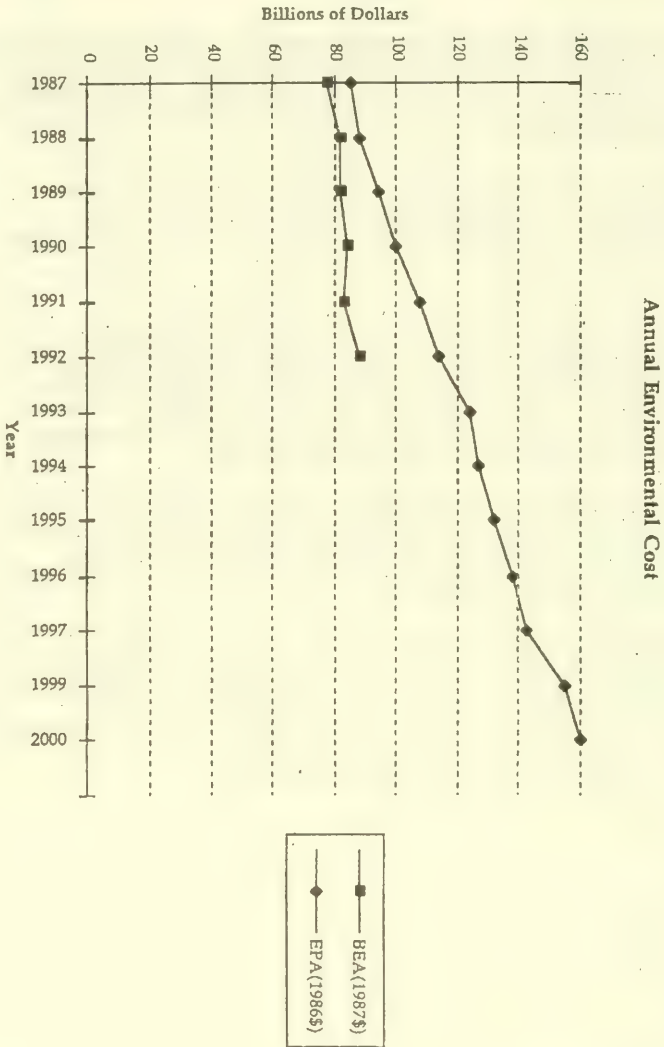
- ACTUAL COSTS ARE LOWER THAN ESTIMATED COSTS: Actual environmental control costs as measured by the Bureau of Economic Analysis have been consistently lower than those estimated by EPA in "Cost of Clean" See attachment 1.

- EVEN ASSUMING THE HIGHER COST OF "COST OF CLEAN" ESTIMATES, APPROXIMATELY HALF OF THESE COSTS WOULD HAVE HAPPENED ANYWAY: Cost include basic services like garbage collection and sewerage that would continue regardless of EPA regulations. For the state and local sector, basic services account for approximately 70 percent of total costs, for the private sector, approximately 30 percent.

- FUTURE PROJECTED COSTS ARE BASED ON THE 1994 REGULATORY AGENDA AND ARE A SMALL ADDITION TO SUNK COSTS. EPA IS HAS ALREADY PAIRED DOWN ITS 1994 REGULATORY PROGRAM AND PROGRAMS LIKE THE COMMON SENSE INITIATIVE WILL LOWER THAT INCREASE IN COST IN THE FUTURE.

- EVEN USING THE HIGHER ESTIMATES AND INCLUDING BASIC SERVICES, ENVIRONMENTAL COSTS ARE VERY SMALL COMPARED TO REVENUES. For the manufacturing sector, the environmental costs are about 0.7% of revenues and for most industry categories environmental costs are less than 0.5% revenues. For no industry category are environmental costs greater than 2% of revenues. See attachment 2.

## Attachment 1



The CHAIRMAN. I would also—I will find the statistics that also indicate that they have come down since we raised the speed limit.

Mr. BROWN. An important statistic, Mr. Chairman.

[Laughter.]

Mr. EHLERS. Reclaiming my time for two comments, first of all I would like to see specific statistics on Corvettes.

[Laughter.]

But more seriously, I just want to reinforce my point. I am not trying to attack the basis of what we are trying to do in the bill, but I do really want to caution that I think we have to take steps, Mr. Chairman, to limit the judicial review aspects in view of the complexity of the issue, the uncertainty of some of the results that we will be seeing, and the lack of public understanding of the nature of risk assessment.

Thank you, and I would be interested in the panel's comments if there is any time available.

Mr. JASINOWSKI. Mr. Chairman, I just wanted to associate myself with the reservations about risk assessment being able to answer all of our problems. I am awfully pleased that that has been raised. It really is only one part, however, of this bill, and I would just say that beyond the risk assessment, Dr. Graham has pointed out one of the most important parts of this bill is that it forces a comparison between risks and benefits, which is very important, and I think there are major provisions in the bill for improving the management of how we do all of this analysis, trying to make it consistent across the Federal Government, trying to force agencies to set priorities. So I look at this bill as one part risk assessment and another part having to do with how we manage analysis in the process of making decisions on regulations.

Mr. EHLERS. Thank you.

Mr. GARNER. In our State Risk Assessment Project I have spent hours in a room full of risk experts, so I just reinforce your position that the answers aren't all there, and the experts don't agree with each other, and you have to at some point listen to all sides of it and go on about your business.

Mr. KAZMAN. In my opinion, judicial review is an extremely important part of this process. You can't be putting agencies on the honor system, say, "Go ahead and study all this, but we are not going to test you." Judicial review is a test by a relatively disinterested judge, and in the past I believe if you look at any statute which has incorporated a cost-benefit requirement and allowed that cost-benefit requirement to be judicially reviewable, the results have generally been good in terms of the amount of regulation issued and the public benefits conferred.

On your second point, I agree, these are not going to be scientific decisions. We are using scientific tools to help us make what should still be recognized as being ultimately political decisions.

In the past the sort of decisions that came out of smoke-filled back rooms, today they would be coming out of smoke-free back rooms, but they are still political decisions, and one thing we should be on guard against is the notion that because they come with all this scientific sounding language that it is scientists speaking. That in the past has tended to make the lay public think, "No reason to get involved. That is what the scientists tell us. That is

what the Government scientists tell us." Really, these are going to keep being political decisions, and that really means that the public should be worried about throwing stones at them.

The CHAIRMAN. The time of the gentleman has expired.

Mr. Geren.

Mr. GEREN. Thank you, Mr. Chairman.

I want to thank the panel for their testimony, and I want to particularly thank Dr. Graham not only for being here today, but he has been available, been very generous with his time over the last couple of years with many Members of Congress, and it has been very helpful to many of us in trying to understand some of these issue, and we appreciate that openness and the gift of your time as well as other members of this panel.

Perhaps this point has been labored to death today, but I would like to just ask the panel to discuss this judicial review issue a little bit more and go from kind of general concerns about it to specific recommendations.

We are doing unfunded mandates on the Floor right now, and in my opinion some of the most credible concerns about the unfunded mandated legislation have been in the area of judicial review, and the Florida debate has developed a lot of concerns that had not been fully aired at the committee level and raised a lot of questions on the Floor, for which many of us who are proponents to the unfunded mandates legislation frankly don't have all the answer to.

So to the extent we can further develop the judicial review issue here today, I think it would be helpful. It is one of the little arcane sides of these kinds of bills that tend to get overlooked in the public debate, and to the extent any further discussion of it would be helpful, I would just like to open the rest of my time to comments from any members of the panel about the issue.

Mr. JASINOWSKI. Well, it is one of the toughest issues that you raise, and the way we are thinking about it at this point, Congressman, is that, one is the question of the threshold and that we need to set that so that we don't have everything going through.

Beyond that, with respect to the criteria, what we are doing is going beyond the administrative procedures law which, as you know, already provides for some form of judicial review, and to suggest that if you look at existing statutes in the Federal Government and look at the different criteria that you can use, you will find it ranges from statements of emergency to statements of criteria about different kinds of health costs and other matters, and by looking at other statutes we think it is possible to develop some general language on judicial review that would allow for the targeted use of it. We will be happy to share our research with the committee as we complete it.

But I think there are laws out there that already provide for judicial review beyond the Administrative Procedures Act which should provide some guidance. It has got to be something between emergency and the Administrative Procedures Act to tell us what it is that makes it important enough-- is it cost, is it health, is it whatever—and I think that would be helpful.

Mr. GEREN. Thank you.

Dr. Graham.

Mr. GRAHAM. Yes, Congressman Geren, the judicial review issue is very important. I think we should think for a moment, let's play out the scenario where there is no judicial review allowed on risk assessment, and think it through. If you are in the agencies and you are engaged in this kind of activity, why are you going to behave any differently in the next 10 years than you have in the previous 10 years if Congress passes these requirements but doesn't authorize any judicial review over the activities and the behavior of those agencies? I think we should be skeptical about whether they are going to behave any differently. So that leans me in the direction of wanting to have some judicial review.

On the other hand, you have heard a number of comments from people, I think, that are quite appropriate that, we don't want judges mucking around and debating on the science and having enormous costs of litigation around what are primarily the technical and scientific issues.

So I would say that you want to have some form of judicial review but you want to make clear in the legislation that you are looking for the judges to defer to the technical expertise, to the agencies, unless there is overtly arbitrary and capricious behavior, which does occur on occasion.

So, yes, I think we need some judicial review, but I think it ought to be under a relaxed standard.

Mr. GARNER. I think that a good and sound peer review process would be a much better substitute than judicial review. If the peer review process is set up and it is done legitimately and it is open, and it is monitored, I think that can be the quality control on the products that come from the agencies.

Mr. KAZMAN. If you are going to have peer review, however, I believe that this issue of agency game playing becomes even more important. If the agency is going to be selecting who the reviewing peers are, who does the selection, they can easily stack the decks in their own favor, and that is why I emphasize that in our view it is important to put the peer review process into OMB's hands. OMB has an institutional function of reining in individual regulatory agencies, and that underlying organic mission in a sense would make it do a much better job on peer review.

But once again, I would suggest that the peer review results themselves be part of the administrative record that go to the court. Remember, agencies always have the fact that the courts give them a great amount of deference, but that has not prevented courts in the past from looking through agency rationales and deciding whether there is, in fact, a solid basis for them. For the agency to simply yell, "It's our administrative expertise, that is how we resolved all these conflicts," has never been enough for a good court, and in the future it still should not be enough.

Mr. GEREN. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Geren.

Mr. Luther.

Mr. LUTHER. Thank you, Mr. Chairman, and again thanks for the presentation. Certainly as a new member, here it is very informative.

I think there would probably be general agreement that in making these decisions, that we would want to have whatever informa-

tion is necessary in order to make the most accurate assessment of risk possible, and I hear you saying that is the direction you are headed.

The question that comes to my mind—and, again, being a new Member of Congress, I am learning this process and how things proceed here, but the question that comes to my mind is whether it would be better to look at each of the underlying laws rather than adding a new standard with potentially new bureaucracy that is kind of a “one size fits all” approach to the regulatory scheme, and I ask the question for a couple of reasons.

First of all, when you get into the different regulatory areas, different disciplines, if our effort here is to get the most accurate information so we can get the best assessment of risk in order to make these difficult decisions of how much resources are we going to spend, how much risk are we going to incur, would it be better to be looking at the individual regulatory disciplinary area? In other words, could we better achieve that standard if we went back to the underlying laws and adjusted the underlying laws to make sure we are achieving that rather than trying to have this sort of “one size fits all” approach?

And then the other reason I ask the question, that same question, but the other reason is, would it be more cost effective to do that? Would we then avoid the potential of ambiguity, which then could result in more bureaucracy trying to resolve the ambiguity, with having one or actually more than one standard, and the potential litigation, and everything else that results when we have kind of this maze of regulation rather than a very clear, defined congressional intent built into a standard?

That is kind of a long question, but that is kind of what I need to hear from you on.

Mr. GRAHAM. Yes. A quick answer. One, the basic principles of sound risk analysis should not change depending on which acronym you are working on; the basic principles should be the same. So I think it is a sound approach to say, regardless of what Federal agency you are in, you are going to use the same basic principles, central estimates of risk based on best available science, reporting of the benefits and costs of regulatory action. Those same basic principles should apply.

Now the problem you get into if you go in your direction, I would say, as an alternative is—well, let's just do this separately for each agency. Then you get into the following paradox. Why is the same chemical, benzene, formaldehyde, butadiene—why do we have a different estimate of risk of that chemical coming from the Occupational Safety and Health Administration than we do from the Environmental Protection Agency? And you talk to these people in these agencies, and they say, “Oh, this is the EPA; we have a different approach to risk analysis here at EPA than we do at OSHA,” and I don't think that Congress wants to foster the idea that they can tailor the way we do risk analysis differently, okay, for each agency when it is the same compound, the same exposure, that is at issue.

So I do want some broad basic principles cutting across the board in this type of legislation.

Mr. JASINOWSKI. What I would add to what Dr. Graham has said is that what we now do is, everybody does their own thing. I mean

that is the way it is done now, and that is part of the reason why we get such enormous wastes, and therefore I would support his view that we need basic consistency across the Federal Government with respect to some principles, and section 3 would, in fact, rather than simply living on its own, it would require that all these other existing laws be changed. So one of the reasons it is an efficient proposal is that it doesn't exist out there by itself. What the legislation would do would be to change the underlying laws in each area so that some consistent principles were applied. I think once you get beyond that level, obviously there is going to be some tailoring.

So I think, Mr. Luther, there is something to the view that you have got to customize some risk at the more microeconomic level, but that is after you have done the broad things right first.

Mr. GARNER. I have to say this. My worst fear about this whole process is, if you escalate the importance of risk assessment beyond that of providing good information to use during your decision-making process, you run the real risk of creating a priesthood of risk assessors in the Federal Government, and instead of doing what you want to do, all of a sudden everything has to go through the priesthood of risk assessors as it does everything else.

So I think that you need to consider how important you want to make this, at least first time out of the box. You know, make it important enough that you get good information, but don't make it so important that you start clogging up the courtrooms and you start empowering a bunch of people with what at times seems to me a voodoo science.

Mr. LUTHER. Thank you.

The CHAIRMAN. Thank you, Mr. Luther.

Mr. Rohrabacher.

Mr. ROHRABACHER. Thank you, Mr. Chairman.

I would like to apologize for not being here during the whole hearing. We had a markup downstairs, and it was a very important markup in the International Relations Committee.

I will be reading your testimony. This is an area of interest to me. I used to be a journalist, and it just seemed to me when we have people who are irrationally focusing on one risk, I mean it is just common sense that we end up, there is a risk, a specific risk, to one individual, and if you focus on that and you so focus on that that you end up wasting resources that should be going into making our manufacturers more competitive, or basically creating new jobs, we have actually put many other individuals at risk we might not even know about, and I think the riskiest population in the United States are people who don't have jobs and people who are poor because they are—well, their nutrition level isn't as well, the pressure is on them as individuals, they drink more because the pressure is on, they might not buy tires for their car—I mean someone told me about that—and we have put all kinds of people at risk by focusing on one set of individuals, and that is what this hearing is all about, and I will be, as I said, reading the specifics in your testimony.

I do have—by the way, just one note, and this is leading up to the question for Mr. Kazman. Every time young people from my district come to Washington, I always meet them, and that is a policy I have, and I have classes of young people coming here, and I

ask them the same question every—every group that comes. I ask them, “When I was in high school in Southern California years ago—30 years ago—is the air today cleaner than it was 30 years ago? Is it about the same as it was 30 years ago? Or is it much dirtier than it was 30 years ago?” And invariably these high school kids give me the same answer, like 90 percent of them say, “It is so much dirtier, it’s horrible, the pollution is destroying—it’s killing us,” and of course the fact is, we all know, those of us who lived through it, the air in Southern California is so much cleaner today than it was when I was in high school, there is just not even any comparison.

Mr. GEREN. Will the gentleman yield for a moment?

Mr. ROHRABACHER. I certainly will.

Mr. GEREN. How old are your high school students? We run them through a lot quicker in Texas.

[Laughter.]

Mr. ROHRABACHER. Thank you. Good.

But the bottom line is that even I think that—not just high school students think this, but I think the large number of Americans have been fed this line, and they think the air—I think a lot of Southern Californians who are adults think the air is a lot dirtier now than it was, and we have had tremendous, tremendous progress in the area of cleaning up the air, and with that in their mind they may be willing to accept all kinds of regulations and all kinds of activities which will in the end be detrimental to not only themselves but detrimental to a lot of other people who may not be able to get a job because they have now accepted excessive regulation.

In other words, they have been told something that is not true, which leads me into my question for Mr. Kazman, and in your testimony and what we just heard a few moments ago, you were mentioning about basically phony science and talking about how we actually—a lot of the decisions that we are making are based on pseudo science of some kind, and you hinted at some sort of political pressure and maybe even went beyond a hint.

What I would like to ask—and I am sorry if this has already been covered, Mr. Chairman—but do you have any examples of scientists or professionals in this area that have been pressured politically, specifically pressured for political purposes, to change their scientific findings?

Mr. KAZMAN. On that specific point, we could give you documentation, I believe, of scientists who, after having testified before one or another subcommittee on an issue and the gist of their testimony was that some global crisis was in fact not all that likely to occur, have been relieved of their duties. I don’t have specific names, but I have read them, and I could supply you with documents on that point.

[The information follows:]



## COMPETITIVE ENTERPRISE INSTITUTE

February 17, 1995

Representative Dana Rohrbacher  
2338 Rayburn  
Washington, D.C.

Dear Rep. Rohrbacher:

At the January 31st Science Committee hearing on H.R. 9, you asked about incidents of government scientists who faced retribution due to their research and views. I promised to provide you with documents on such cases. The enclosed documents described what happened to the following individuals:

National Science Foundation Assistant Director David Kingsbury, due to his position on biotechnology policy;

Department of Energy scientist William Happer, due to his views on ozone depletion and global warming;

Agriculture Department scientist Sherwood Idso, due to his views on the effect of rising CO-2 levels on vegetation;

NAPAP and EPA advisor Edward Krug, due to his views on acid rain.

I hope these prove of interest. Please let me know if you have any questions.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Sam Kazman', written over a horizontal line.

Sam Kazman  
General Counsel

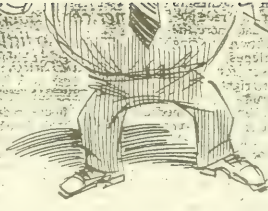
ld have them believe little technical in elaboration, no, his crusade against as President Reagan's win in Southside Virginia Beltway. But his brand of party members usually reflect the state as polls show he could win out Mr. North is that he sues right down the line the mischief of the Com or the effect of environments in the Shenandoah Valley him with a George

that energizes his backdated press attack on him at to mention opposition and the financial establishment than liberal populist back in the 1970s. Even though ordinarily does not in presidential election heavily on Mr. Miller's day. No one apparently after when it comes to less campaign work for us win more seats in the an ever before. It's only here's a problem.

Independent bunch, not editorialists, politicians is necessary to tell delegates about bolting the party, so forth. They would do when they consider Mr. men have served the past. Both can do so

nal conflicts within the Bess' attempt to set up e, but the details of their . What is relevant is the Hamad continues to

have served, for one, to rion call to rage in the strategy paved the road hamad's world new November when as a an he called Jews "the community. He managed once the pope and urged all whites. It is the kind hat has become closely of Islam's philosophy. furor caused by Mr. ech, Mr. Farrakhan susling what he called the n effect tacitly giving d continues to speak for in old one. It is to capi-people feel in their lives. rides them someone to 'philosophy that deepens itations, only more rage. he crowd with weapons otiators is no surprise.



## Letters

6/2/94 Wash. Times

### Claims of a Gore-led smear campaign are fantasy . . .

I respond to your May 20 editorial "What did Mr. Gore have in mind?" You inaccurately portrayed how my dispute with Professor Fred Singer began and how it ended.

I can easily answer your question about what Al Gore had in mind when he telephoned me in June 1992. He wanted to know if Professor Roger Revelle had changed his opinion in the last year of his life about the seriousness of the global-warming risk. I said, "No, he didn't." As Mr. Revelle's closest junior colleague during his last 10 years, I was a sensible person to call. This makes me neither a Gore "associate" nor his "ad hoc science adviser." To suggest that either of us contemplated a smear campaign is fantasy.

Your editorial wrongly attempts to link my interaction with Mr. Gore

and Gore staffer Katie McGinty to the very separate circumstances that led to my dispute with Mr. Singer. My communication with Mr. Gore and Ms. McGinty concerned Greg Easterbrook's attack on Mr. Gore in the New Republic. My interaction with Mr. Singer involved a completely different situation; namely, republication of an article from the house magazine of Washington's Cosmos Club in the CRC Press volume, an issue that came to a head months later. I could not have offered earlier objection to the article's inclusion because it was not proposed in the original list of chapters.

Professor Charles David Keeling and I worked together to respond to Mr. Easterbrook's distortion of Mr. Revelle's views in the New Republic. I did communicate with Ms. McGinty, out of respect for

then-Sen. Gore's relationship with Mr. Revelle. Quite contrary to your editorial insinuation, my faxed note to her meant, "Is this what the Senator had in mind, an assessment of Revelle's views without reference to Singer?" Mr. Keeling and I had agreed to avoid comment about Mr. Singer, as evidenced by our draft letter. I understood Ms. McGinty to prefer this approach, too.

Your suggestion that I was forced to settle this lawsuit is untrue, and it reflects a misunderstanding of the settlement process. It was not a court that put a halt to these proceedings, but rather a mutual decision by Mr. Singer and me, absent any court involvement. For numerous reasons, two men sought to resolve their differences.

JUSTIN LANCASTER  
Lexington, Mass.

### . . . Gore and his minions punish civil servants who dare to disagree

Your May 18 editorial "What did Mr. Gore have in mind?" raised the specter that Vice President Al Gore, his staffers and hangers-on have maliciously undermined and misrepresented a scientist's view on global warming.

To those who have been associated with science and technology in the federal government, this comes as no surprise; many would consider it far from the worst Mr. Gore et al. have done. In order to bias federal science and technology policy and to purge the civil service of dissenting views, the vice president and one of his senior aides have interfered in federal personnel matters in ways that are, at the least, unethical.

Mr. Gore's adviser for domestic affairs, Gregory Simon, while a congressional staffer during the late 1980s, trumped up phony charges of conflict of interest and hounded from government an outstanding assistant director of the

National Science Foundation, David Kingsbury, because the two clashed on biotechnology policy. Recently, when Mr. Kingsbury sought to return from the private sector to a civil service position for which he was eminently qualified, Mr. Simon, while working for the vice president, threatened a high-ranking official of the Department of Energy with retaliation if she were to hire him.

Also while the vice president's adviser, Mr. Simon tampered improperly with a senior civil servant at the Food and Drug Administration, causing him to be removed from his position, as retribution for the "transgression" of having been highly effective at implementing official government policy during Republican administrations.

Finally, Mr. Gore himself dismissed William Happer, a high-level scientist at the Department of Energy, because Mr. Happer refused to

ignore the scientific evidence at hand and parrot the vice president's pet theories on ozone depletion and global warming.

It is probably too much to expect that government will ever reach a level where personnel decisions are made largely on the basis of merit, but a return to behavior reminiscent of the revanchist mentality of the Nixon White House enemies list certainly moves us further from that ideal. When he speaks of "reinventing government," is what Mr. Gore really has in mind the authoritarian mean-spiritedness of H.R. Haldeman, John Ehrlichman and Charles Colson?

HENRY MILLER, M.D.  
Palo Alto, Calif.

■ Dr. Miller is a visiting scholar at Stanford University's Hoover Institution and a visiting fellow at its Institute for International Studies.

— The Editor

THE WALL STREET JOURNAL TUESDAY, MAY 25, 1993

## 'se Olympics Bid Pressure China on Human Rights

By ALBERT R. HUNT

inning for president, Bill Clinton recently stressed the primacy of global issues and the need to emphasize human rights in international relations. One of these two themes are on a head-to-head as President Clinton wrestles whether to continue China's current status. The Chinese have so far not their most favored nation, or status only because President Clinton—overrode congressional intent to link the tariff treatment of goods with human rights record.

Mr. Clinton, who faces a June 12 election, the China situation is a critical test of how he reconciles his conflicting goals. The annual growth rates of about 10%, according to a new international survey, is now estimated to be the world's third-largest economy. It is well on its way to becoming the appealing market. Yet if the issue of human rights matters—and it surely does—what sort of nation is China's abominable record certainly against the U.S. adopting a business-usual attitude.

There is a way out of this dilemma for Clinton. He should extend China's status—which, despite the name, is accorded to most of our trading partners—while attaching mutually acceptable human rights conditions. At the time, though, he should forcefully reiterate China's bid to get the 2000 Olympics until its human rights record improves dramatically.

The International Olympic Committee decided the location for the 2000 Games between, and Sydney, Australia, and Beijing are the front-runners. Denying the privilege of hosting the Games would impede economic liberalization in China and thus wouldn't hurt citizens. But China's rulers—the ones being—would see a clear sign that their human rights record, including of arms to would-be world remakers are unacceptable. Democratic Sen. Bill Bradley of New York, who's on the verge of revising his opposition to MFN, observes that a desperately wants the Olympics as of escaping the world-wide stigma of the 1989 Tiananmen Square massacre. The U.S. ought to immediately start trying to deny this, unless the human policy is changed," says the senator, member of the gold-medal-winning U.S. Olympic basketball team.

China's human-rights record certainly is a reason to renew its MFN status. "mocracy dissent still is brutally stifled," says a human rights agency, that at least 40 people were secretly "died last year" "purely for having had the audacity to challenge, in an extremely full manner, the [Communist] 30 time honored monopolies on power and truth." "They are reliable as that China has broken its word still using prison labor to make it ships to the U.S. And repression against people of Tibet continues." MFN should be given because it American companies and consumers—even though it does. With almost 1 billion Chinese exports coming to U.S. annually, it's estimated that ending China's favorable tariff treatment cost U.S. consumers billions of dollars. The likely Chinese retaliation also means thousands of lost jobs and a sizeable \$6 billion of investment. U.S. companies now have in China, a better price to pay to get it after China's accession to the

By HOLMAN JENKINS JR.

As the Department of Energy's top scientist, William Happer Jr. was popular on Capitol Hill and well regarded among his peers. Senate Democrats even urged the Clinton folks to keep him on, but the Bush appointee got the ax anyway. In the words of a top Democratic staffer, Mr. Happer is "philosophically out of tune" with the new administration.

Translation: He doesn't share Vice President Al Gore's belief in an impending environmental cataclysm.

Nobody in politics has a bigger investment in ecological pessimism than Mr. Gore. It was the avowed basis of his presidential bid, the theme of his best-selling manifesto, "Earth in the Balance." He may come across as a solemn figure on television, but you don't get to the big leagues without playing hardball.

Every administration has the right to pick its own appointments, and Mr. Gore has gone to town. Carol Browner at the Environmental Protection Agency helped write his book. The "green" spot on the National Security Council has gone to Ellen Claussen, EPA's former top air quality guru. Rob Watson was NASA's chief of ozone hysteresis; now he's been plucked out for a job in the White House. The policy results are already showing up. Mr. Gore and his crowd are crusading for limits on greenhouse gases over the objections of green-hausers at Treasury and DOE.

### Attack on Heterodoxy

You can't make sound environmental policy without sound science, which makes Mr. Gore's intolerance of scientific heterodoxy troubling. Mr. Happer is agnostic on the inner workings of his dismissal as DOE's director of research, but he's been impolitic about Mr. Gore's pet causes. Especially global warming and the dreaded ozone hole.

He says that while global warming makes an interesting hypothesis, "I don't see the data that say it's the end of the world." Lately he's been sticking studies under congressional noses that show a slight decline in the ultraviolet radiation hitting the Earth's surface, the opposite of what the ozone alarmists predict. And he may have annoyed Gore staffers in a recent meeting by questioning whether spy satellites really have a useful role to play in ecological monitoring.

While the Clinton administration is swinging one way, scientific opinion is swinging the other. There has been a great sobering up since the climate hysteria of the late 1980s. Many scientists now realize that they were taken in by media

hype and computer simulations whose deficiencies they didn't really understand. "We can lose our objectivity as easily as anybody else," says NASA's John Christy.

The now-fading outbreak of climatic doomsterism just shows that not even scientists are immune to the suggestive power of the media drumbeat. And Mr. Gore has been an eager drummer. Four years ago, he declared that there is "no longer any dispute worthy of recognition" about the planet's imminent destruction, and called for the country to assume mind-boggling costs to ward off the apocalypse. In a series of "roundtables" ending last year, he used his chairmanship of a key Senate subcommittee to intimidate skeptical researchers

*While the Clinton administration is swinging one way, scientific opinion is swinging the other. There has been a sobering up since the climate hysteria of the late 1980s.*

and promote a phony image of scientific unanimity behind his scary talk.

The research community still buzzes over his flaying of Sherwood Idso, an Agriculture Department research physicist who argues that rising levels of carbon dioxide (the main greenhouse gas) would spur Earth's vegetation to greater feats of growth and reproduction; the plants would become greener and reabsorb the carbon dioxide that might otherwise cause global warming. Mr. Idso is regarded as a bit of a zealot by some fellow scientists, but he has written hundreds of peer-reviewed papers and nobody questions his methodology.

Two years ago, he was dragged before Mr. Gore's subcommittee and accused, in effect, of being a scientific shill for earth-raping coal companies. "A Gore staffer told me that the hearing was going to be an 'exploration of views,'" says another scientist who testified that day. "But actually the whole purpose of the hearing as far as I could see was to hammer Idso. As for a career scientist from DOE who was also present: It was a setup."

Mr. Idso got the message, says his fellow researcher, Robert Balling of the Office of Climatology at Arizona State University. "He came back and said, 'I'm going to cool it.'" On pursuing controversial research. Others took home the same lesson. "It sure as hell had a chilling effect on me," says one scientist. "I would be very reticent to cross Gore."

Richard Lindzen, an MIT meteorologist and a scathing critic of the computer models that predict climatic disaster, was another target. In one hearing, Mr.

Lindzen withdrew one of several technical objections to the models. Mr. Gore insisted on the record that Mr. Lindzen had retracted his opposition to global warming, then fired off the unpublished transcript to columnist Tom Wicker, who repeated the canard in the New York Times.

Mr. Gore has had an easy time recruiting playmates for these airplane games from the scientific community, notably at NASA, an agency devoted to search of funding and a mission.

It was NASA's James Hansen who showed up before Mr. Gore's subcommittee with a trumped-up story about how the Bush White House had tried to "censor" scientific testimony. It was Mr. Hansen who threatened, in the hot summer of 1988, that Mr. Gore's greenhouse bill arrived. And just last year, NASA produced a dire new ozone warning, prompting Mr. Gore to make his famous grandstand play about an "ozone hole over Kenebunkport." The study had been rushed out without proper vetting, and the predicted hole never appeared.

Mr. Gore may genuinely believe the world is coming to an end, but his resort to show trials and other propaganda stunts reflects a long pattern of tactical cynicism. When the Reagan folks were proposing to charge market prices for Tennessee Valley Authority electricity, Mr. Gore invited White House economist Bill Niskanen up for a "private" chat that turned out to be an impromptu hearing in front of TV crews from communities around the country. Later Mr. Gore helped pass a law making it illegal for federal employees even to discuss market pricing.

### Besotted With Metaphors

When it comes to environmental matters, shutting out contending voices is raised to high principle. Mr. Gore, who is besotted with metaphors, sees an ecological "holocaust" coming and implies that the media ought to play down the scientific "uncertainties" lest they "undermine the effort to build a solid base of support for the difficult actions we must soon take." He told the Atlanta Constitution last year that "only a few old scientists" doubt that an environmental crisis is at hand.

In fact, pretty nearly the opposite is true. Even Michael Oppenheimer of the frequently alarmist Environmental Defense Fund concedes that there's no ozone catastrophe in the offing. And as climatologists begin gazing up from their computer models at the real world, global warming looks like a flash in the pan too.

It's worth remembering that Al Gore wasn't interested in letting us even get to this more reasoned assessment, that he had already moved on and was shrilly demanding that society be turned upside-down over hypothetical disaster scenarios. Now this same Al Gore is a heartbeat from the Oval Office.

*Mr. Jenkins is a contributor to the Journal's editorial page.*



William Happer Jr.

## Cambodia's Potemkin Elections

By CARR MURPHY

PHNOM PENH The whole world is rooting for Cambodia, who is in the midst of its first elections in 21 years. Yet the elections, which continue through Friday, cannot and will not provide either peace or a good government.

Part of the reason for this becomes apparent in Chum Khiri, south of here. In a 6 a.m. raid on Sunday, according to Chief Cpl. Roy Jewiss, a British member of the United Nations military forces, about 80 Khmer Rouge guerrillas came down from the Elephant Mountains to attack workers setting up an election booth. Three were

to attend political rallies, to delaying the broadcast of another party's TV station, to shooting people.

"The pressure is stronger and stronger," says Ok Serey Sopheak, spokesman for the rival Liberal Democratic Party. "It's a case of a vote for a seat in Phnom Penh, east of villages where people used to greet us openly, with smiles, now they turn their back to us. It was obvious those villagers had been under hard pressure from local authorities."

The main claim to power of the Cambodian People's Party is that it says it can

of the seriousness with which they regard its mandate. The campaign was "a great success," said Mr. Akashi on Thursday. "The basic minimum conditions [for an election] are therefore in place."

But elections are not supposed to be merely feats of logistical prowess. In Cambodia, the point is to establish a legislature that can govern the country, keep it together and make peace. It is in this sense that the election, like the Potemkin elections—a wonderful display that hides a dismal reality.

Still, the elections grow forward, undeterred by the rude realities that have in-

## POLITICAL SCIENCE

BY RONALD BAILEY

Last spring physicist William Happer found out what happens to federal scientists who ask the wrong questions. He was fired.

Happer, director of energy research at the U.S. Department of Energy for two years, was asked to leave at the end of May. Although he was a political appointee, he had expected to remain until his replacement was nominated, since the Clinton administration had asked him to stay on in January. But he was pushed out two months beforehand. "I was told that science was not going to intrude on policy," he says. Now the DOE's former chief scientist is back at Princeton.

Happer made the mistake of crossing Vice President Al Gore, the Clinton administration's ranking environmentalist. In April, Happer testified before the House Energy and Water Development Subcommittee on Appropriations. "I think that there probably has been some exaggeration of the dangers of ozone and global climate change," he said. "One of the problems with ozone is that we don't understand how the UV-B is changing at ground level, and what fraction of the ultraviolet light really causes cancer."

Happer's cautious testimony was at odds with Gore's alarmist views. "Like an acid," Gore warns in his tome *Earth in the Balance: Ecology and the Human Spirit*, chlorine from man-made refrigerants called chlorofluorocarbons (CFCs) "burns a hole in the earth's protective ozone shield above Antarctica and depletes the ozone layer worldwide." Gore predicts that ozone depletion will damage crops and raise skin-cancer rates.

Gore's expectation is superficially plausible. Stratospheric ozone stops much of the sun's ultraviolet-B light from reaching the earth's surface, where excessive amounts can harm plants and animals. Sunburn is the type of UV damage with which most people are familiar. And recent satellite data indicate that ozone declined by 3 percent to 5 percent over the United States and Europe between 1979 and 1991.



William Happer, fired by the Energy Department for questioning Gore's line on ozone

But such a small decrease is hard to extract from the satellite data, since ozone levels vary widely depending upon seasons, latitude, and sunspot activity. (See "The Hole Story," June 1992.) For example, the amount of UV naturally reaching the ground in Florida is twice as great as that in Minnesota. A 5-percent depletion of ozone would increase UV-B exposure by the same amount as moving a mere 60 miles south. Few people worry about moving from Philadelphia south to Baltimore because of the resulting increase in UV-B exposure.

In any case, if stratospheric ozone is declining, more UV-B sunlight should be reaching the earth's surface. But there's no evidence that the planet is experiencing an increase in surface UV-B, and this is what puzzles Happer. "We have lots of lovely measurements of upper layers of ozone in the stratosphere, but when we look around at what we know about ultraviolet light, the data is very sparse and what data we have shows very little change," he testified. "If anything, it shows a slight decrease." Researchers have found that the amount of UV-B reaching the surface of the United States has declined by between 5 percent and 18 percent over this century.

What's going on? Perhaps UV-B is being blocked by industrial haze or an increase in cloud cover. Whatever the cause, it seems that such a contradiction between the satellite data on ozone and ground measurements of UV-B levels cries out for further investigation. At least that's what Happer thought.

"Why not measure directly the thing that worries you, which is UV-B at the surface, not just reductions in stratospheric ozone?" he asks. DOE, under Happer's direction, developed an Ozone Project to build an improved network for measuring UV-B at ground level. But Happer soon discovered that's not the way science works in Washington, D.C. He says the ozone alarmists in the Clinton administration "want to declare victory and make sure that no one second-guesses them."

Happer's problems were all the worse because he had earlier tangled with America's ozone czar, Robert Watson. Watson was the chief scientist for NASA's Mission to Planet Earth program and served as the head of the Ozone Trends Panel. He is also a favorite of Gore's. In his book, Gore praises Watson for his "steadfast work" on stratospheric ozone. And Watson has now reaped his reward: He has been nominated to become associate director of environment in the White House Office on Science and Technology Policy.

Happer recalls a run-in he had with Watson during a meeting last year of the Federal Coordinating Council on Science, Engineering, and Technology, chaired by Allan Bromley, President Bush's science adviser. Watson made a scary presentation to the council in which he warned that ozone depletion would lead to perilous ecological problems and increases in skin cancer. Watson suggested that an "ozone hole" could open up over Kennebunkport, Maine, Bush's vacation home.

Atmospheric scientists think chemical reactions involving CFCs are responsible for the infamous "ozone hole" over Antarctica, a 50-percent drop in ozone levels

during September and October. Chlorine released from CFCs destroys ozone in very cold stratospheric clouds in the presence of springtime sunlight over Antarctica. Ozone destruction stops once temperatures warm up, and ozone returns to near-normal levels during the summer months.

At the meeting, Happer angrily protested Watson's "exaggerations." He pointed out that during the Antarctic ozone hole the amount of UV-B light reaching the surface is far less than that reaching the surface at the equator. Happer noted that the richest fishing area in the world, just off the coast of Ecuador, receives "a thousand times more UV-B radiation than do the oceans around Antarctica during the height of the 'ozone hole.' Yet many of the same species of phytoplankton thrive in both areas with little or no apparent

damage." Watson backed down from his most outrageous assertions. But this dispute earned Happer a powerful enemy.

Happer believes that others in Gore's coterie may have been out to get him. "I was told that [Kathleen] McGinty has an enemies list and that I was on it," says Happer. McGinty, a legislative assistant to Gore when he was in the Senate, is now the director of the White House Office on Environmental Policy.

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**The data actually show a slight increase in ozone, says Happer. And the amount of UV-B light reaching the United States has in fact declined between 5 percent and 18 percent this century.**

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Not only did Happer question the administration orthodoxy on ozone depletion, he also questioned how serious the biological effects of increased UV-B might be. "A thinner ozone layer allows more ultraviolet radiation to strike the earth's surface," Gore warns in *Earth in the Balance*. "Many life forms are vulnerable to large increases in this radiation, including many plants."

But Happer notes that recent work at the Brookhaven National Laboratory shows scientists have been seriously overstating the harm that UV-B causes plants. The Brookhaven biologists exposed alfalfa seedlings to UV-B radiation and then measured the damage to the seedlings' DNA. They found that UV-B damage to the alfalfa was less than half that of the widely used baseline for UV-B damage in plants and between 10 and 100 times less than the damage found in a standard test using unshielded DNA. In a report published in the August 1992 *Nature*, they wrote: "Our results indicate that plants are not among the most sensitive biological targets" for UV-B. Consequently, the threat posed by reduced stratospheric ozone to plants is far

less than the eco-alarmists have claimed.

This good news has not been greeted with universal acclaim. Happer says that one of the Brookhaven researchers "got anonymous phone calls late at night at home calling her a 'Reaganite fascist pig.'"

Happer describes the officially accepted approach to climate policy this way: "When you ask this gang overseeing ozone depletion and global warming how much two plus two is, they first ask, 'Why

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**Instead of policy being guided by factual information, scientific facts are being forced to fit the environmental policy requirements of certain politicians, bureaucrats, and activists.**

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do you want to know?' Then you say, 'Well, I'm interested in finding out what's happening to the ozone layer, and I thought the answer would help.' Then they say, 'Well, how much do you want it to be?'"

In the worst cases, science has been turned on its head. Instead of policy being guided by factual information, the facts are being forced to fit the policy requirements of certain politicians, bureaucrats, and activists. "With regard to global climate issues, we are experiencing politically correct science," Happer says. "Many atmospheric scientists are afraid of their funding, which is why they don't challenge Al Gore and his colleagues. They have a pretty clear idea of what the answer they're supposed to get is. The attitude in the administration is, 'If you get a wrong result, we don't want to hear about it.'"

*Contributing Editor Ronald Bailey is the 1993 Warren T. Brookes Fellow in Environmental Journalism at the Competitive Enterprise Institute. His book ECO-SCAM: The False Prophets of Ecological Apocalypse was published by St. Martin's Press this year.*

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TIMES

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## Political cleansing at the Energy Department

**A** scientist seeking data that could have put "Ozone Man" Al Gore out of the scare business is himself out at the Department of Energy. William Happer Jr., DOE's director of energy research, will be leaving the agency soon, and, reports the trade press, Vice President Gore's office pushed him out.

Inside Energy, a newsweekly devoted to federal energy issues, reports Mr. Happer was fired after a confrontation with Gore staff over the need for more information on the amount of ultraviolet radiation reaching the Earth's surface. Such data would be useful because people like Mr. Gore have long argued that ozone depletion means more harmful UV rays reach the Earth. And more harmful UV rays mean more people with killer tans. So the vice president has pushed to get rid of the chemicals — chlorofluorocarbons or CFCs — that allegedly made Swiss cheese of the ozone layer. Out went all manner of spray-can propellants, refrigerants and more.

Mr. Happer pressed for additional means to collect data to find out if, in fact, more UV rays really were striking the Earth. But he won't be at the Department of Energy to find out, because the administration has abruptly notified him he is being replaced. In an interview, he told this paper he could not remember any confrontation with a Gore staffer and played down any political angle to his departure, saying that Energy Secretary Hazel O'Leary had the right to bring in her own people. He could not say whether his views about the need for more data played any role in his departure, only that he hoped the agency would collect them in his absence.

A congressional staffer familiar with Mr. Happer said the Bush holdover was respected on Capitol Hill and that his departure was "mysterious." "I know the Clinton people originally asked him to stay, and I know

he wanted to stay. Then, all of a sudden, he is going," said the staffer. Inside Energy says it stands by its story.

There's no mystery about Mr. Gore's interests in all this. The vice president has been making a nice living with tales that scared Americans out of their pocket-books. Remember the ozone hole that wasn't last year? Then-Sen. Gore joined up with the National Aeronautics and Space Administration to play up warnings of vast amounts of atmospheric ozone-destroying chemicals into the infamous "ozone hole over Kennebunkport." He spoke ominously of blind fish in Patagonia. A panicked Congress hastened the phaseout of the bad old chemicals.

In the end, of course, there was no hole and no need for the phaseout that left Americans scrambling for more expensive, less effective substitutes. But the country is stuck with the bill for converting to non-CFC systems, a cost that runs into the tens of billions.

To date, there is no evidence of increased ultraviolet radiation on the Earth's surface. A 1988 study in Science magazine found that if anything, UV exposure from 1974-1985 actually went down. A 1991 study backed by American and international agencies reported findings along the same line.

There isn't much sign of ozone depletion either. Washington Post staffer Boyce Rensberger recently reported that things were much better than the Gores of the world led us to believe: "In fact, researchers say, the problem appears to be heading toward solution before they can find any solid evidence that serious harm was or is being done."

Environmentalists are trying to declare victory and get out, to paraphrase an old military line, before Americans figure out they have been had. One way to do that, unfortunately, is to keep scientists like William Happer from doing their jobs.

CONGRESS

Letter

Clinton

The principle of control of the military by inordinate del pointment of seci military departme

Such delays are out of the Clinton's the correct gende management posit serious implicatio of civilian control. istration can move speed to fill key p and months of d Pentagon to get u that military depar perfectly well w secretaries. If the unnecessary durin months of a new the question of wh all is bound to aris

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## Stopping D.C. contract abuse

**T**he D.C. government's procurement practices long have been the gateway to a black hole of

they were paying for. A thriving rule in government seems to be that it is easy to write the check without

credit nuclear weapons complex, would increase from \$5.5 billion to \$6.5 billion.

Emphasizing Clinton's—or perhaps Gore's—"green" views, the big winners at DOE would be solar and other renewable energy sources (up 1% to \$327 million) and biological and environmental research (up 17% to \$416 million). Losers include nuclear energy research, whose current \$345 million budget is to be lopped in half, as well as basic energy sciences, which would fall about 2% from its 1993 figure of \$814 million. In particle and

nuclear physics and in fusion research, the bottom lines show small gains in most instances, but even there the increases go for construction, leaving the core science programs with little more than cost-of-living gains of around 3%. The budget seeks \$20 million to start work on the Tokamak Physics Experiment at the Princeton Plasma Physics Laboratory, \$26 million to begin the Advanced Neutron Source at Oak Ridge National Laboratory and \$36 million to create an asymmetric "B-factory"—an accelerator producing B

mesons—which would go up at either SLAC or Cornell University. Fermilab, which wanted \$400 million to hasten the upgrade of its main injector, may have to settle for the \$25 million in DOE's budget, and the SSC under Clinton's plan would get not the \$280 million called for in the building program but \$640 million and a stretchout of three years. Worse, the venerable Los Alamos Meson Physics Facility is to be scrapped, with just \$1.5 million allowed for closing it down.

—IRWIN GOODWIN

*Physics Today* June 1993

## HAPPER LEAVES DOE UNDER OZONE CLOUD FOR VIOLATING POLITICAL CORRECTNESS

These are turbulent times in Washington for science. Consider the case of William Happer, who was dismissed from his post as director of energy research at the Department of Energy after opposing the prevailing views of Vice President Al Gore Jr. and his environmental aides on the harmful effects of ozone depletion and greenhouse gases on the Earth's environment and on human health. Happer's dispute with Gore's people is the first instance of the Clinton Administration enforcing its version of "political correctness" on scientists in its midst. The sacking of Happer, a former Princeton University physics professor with impressive credentials, raises questions about whether the Administration will be able to recruit scientists for sensitive positions when science conflicts with politics.

As a holdover from the Bush Administration, Happer was not expected to stay on in the Clinton Administration. The White House could easily have dumped him in favor of its own choice for top scientist at DOE. Instead, after President Clinton's inauguration, Happer was asked to remain at his post until a successor could be appointed. Energy Secretary Hazel R. O'Leary, a former electric utility lawyer and energy regulator in the Ford and Carter Administrations, as well as John H. Gibbons, the President's science adviser, had received enthusiastic messages about Happer from scientist members of the Clinton transition team, from DOE lab directors and from lawmakers in Congress. They called for Happer to be kept on. O'Leary agreed to hold on to Happer, and so did Gibbons, but Gore and his teammates thought otherwise. As George Brown Jr., the California Democrat who heads the House Committee on Science, Space

and Technology, observed: "Happer marches to a different drummer than Al Gore. Will is a pure scientist. Al Gore is a politician."

Widely regarded as a leading authority on laser spectroscopy and optical pumping of spin-polarized nuclei, Happer was plucked from Princeton by the Bush White House in May 1991 to serve at DOE (PHYSICS TODAY, September 1991, page 65). He was confirmed easily by the Senate in August of that year. Even so, the job was not expected to be easy—and as it turned out, it wasn't. Sidney Drell, deputy director of SLAC, had it exactly right when he forecast that Happer was "stepping into a caldron" at DOE. One of Happer's first assignments was to get the nuclear and particle physics communities to agree on scientific priorities in the face of severe budget restraints. He was distressed to find he couldn't obtain consensus.

### Opposing an apocalyptic vision

Signs of Happer's heterodoxy on prevailing environmentalist positions first appeared at a meeting of the Federal Coordinating Council on Science, Engineering and Technology more than a year ago, during the Bush Administration. On that occasion he opposed the apocalyptic vision of an environmentally ravaged Earth, the theme of Gore's best-selling book, *Earth in the Balance: Ecology and the Human Spirit* (Houghton Mifflin, 1992). At the meeting Robert T. Watson, then chief scientist for NASA's Mission to Planet Earth (which uses satellites to study global climate change), delivered a scary account of increases in greenhouse gas emissions that could cause global warming and of exposure to cancer-causing ultraviolet radiation resulting from atmospheric ozone depletion. When Wat-

son spoke of an "ozone hole over Kennebunkport," President Bush's summer retreat, Happer, visibly angry according to eye witnesses, interrupted the discourse, calling the concept rubbish, only using a more colorful epithet.

Happer argued that knowledge of the interactions controlling climate and understanding of abrupt atmospheric perturbations are incomplete and inexact. For starters, he urged RSCET to endorse setting up a network of instruments to monitor the "discrepancy" between predicted levels of uv-B, normally blocked by stratospheric ozone, and the actual levels of uv-B measured at the Earth's surface. Happer explained that most of the ground measurements of uv-B are now made at airports, where chemical pollutants in the ambient air are apt to upset the readings.

The RSCET incident quickly became a cause célèbre among Washington environmentalists. The staff of the Senate Subcommittee on Science, Technology and Space, which Gore headed at that time, characterized Happer's doubts about the extent of a greenhouse effect as "the Bush White House effect."

After Clinton's election, Happer continued to press for new and better placed instrumentation to measure uv-B. Among those who reviewed Happer's ideas on this subject was Watson, who is rumored to be in line for a top job at the White House Office of Science and Technology Policy. It also was looked at by Kathleen McGinty, who served as legislative assistant for energy and environmental issues for Gore in his last years in the Senate and is now director of the newly formed White House Office of Environmental Policy, created at Gore's insistence. The response, not

surprisingly under the circumstances, was that Happer's advice was no longer needed.

Happer, for his part, refused to be silenced. At a hearing on 26 April before the House Appropriations subcommittee on energy and water, Happer once more advocated additional instrumentation to measure uv-B. "What little data we have shows very little change [in the amounts of uv-B reaching the ground since the discovery of ozone holes] and, if anything, a slight decrease," he told the subcommittee. Later, in response to questions from panelists, Happer indicated he is at odds with the Vice President's views on global warming and declared that better scientific evidence of the phenomenon is needed before mitigating measures are taken. "As an individual I think there has been an exaggeration of the dangers of ozone depletion and climate change," he said, making a distinction between his opinions and official Administration policies.

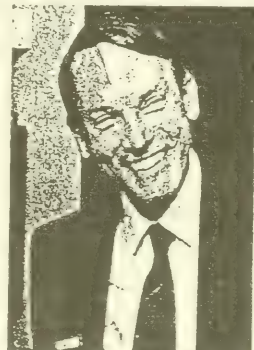
#### Evaluating the uncertainties

Scientists continue to disagree on whether increased levels of CO<sub>2</sub> will be harmful or beneficial, Happer said at the hearing. He referred to climate models by Robert A. Berner, a Yale geophysicist, showing that even in the Mesozoic and early Paleozoic periods, when CO<sub>2</sub> levels were much greater than today's, the Earth was "a reasonable place to live." Arguing from Berner's work, Happer said the geochemical carbon cycle calculated over 570 million years supports the contention that wide variations of CO<sub>2</sub> in the ocean-atmosphere system have been associated with a succession of "greenhouses" and "icehouses" over extremely long time scales.

Happer also sided with those atmospheric scientists who are critical of NASA's planned Earth Observing System, an array of satellites on board orbiting space platforms that might cost as much as \$30 billion to build, launch and operate. EOS would monitor the critical climate variables in the Earth's atmosphere, on its land surface and in its oceans to enable world leaders to make informed decisions on global climate change. The trouble is EOS is still years off, and meanwhile, said Happer, targeted studies of atmospheric change could be made from aircraft, from ships and from the ground. In fact, Happer told the House panel, DOE is already engaged in a "major initiative" to improve the scientific understanding of climate change. His offhand remark was hardly a throwaway line. In effect, Happer

had announced a turf war among several agencies over the topic.

Such statements simply emphasized that Happer was on his way out and he was not leaving quietly. In an interview, he said, "It seems to be an act of treason to propose that there is a great deal of interesting and useful research that needs to be done on the origin, extent and effect of greenhouse gases." Before leaving DOE at the end of May, Happer discussed some of his views about his 22 months in government service. Relaxed in a leather armchair at a corner of his bare-walled office on the seventh floor of the Forrestal Building in Washing-



Happer: 'A hard act to follow.'

ton, Happer spoke with candor and some courage. Those who know Happer well say he possesses little guile and even less patience.

He said he would have preferred to remain on the job a while longer, in part to shepherd the Superconducting Super Collider through this year's budget process. He is "very worried," he stated, about the prospects for the SSC in Congress. Not only is the SSC good science, he asserted, but the machine needs to be completed because the US needs to "follow through on its commitments. We made a bargain with our own citizens in Texas, with taxpayers in the rest of the country and with the world's particle physicists. If the Federal government were to back out now, I would not be able to hold up my head. This feckless, on-again-off-again behavior of the government is something I neither like nor understand... As an American, one who isn't a high-energy physicist, I'm confident we can build it ourselves, without foreign assistance, if we had the will.... If the SSC goes down this

year, it will pull down other physics facilities under construction or under consideration—the Relativistic Heavy Ion Collider [at Brookhaven], the Advanced Neutron Source [planned for Oak Ridge] and the B-factory. If the SSC falls, the rest will go, like so many dominoes."

Happer expressed concern about DOE's ability to "manage its mortgages" on all of its new and proposed physics facilities. He said construction of the \$2.7 billion ANS at Oak Ridge should have been delayed a year or two. He also questioned the inclusion in the fiscal 1994 budget request of an asymmetric B-factory, a colliding-beam accelerator that would produce B mesons. SLAC and Cornell University have spent two years competing to build it. A scientific committee selected jointly by DOE and the National Science Foundation, and operating under the chairmanship of Stanley Kowalski of MIT's Bates Laboratory, is meeting this month to evaluate the technical merits of each design; it expects to have its report finished by 15 July so that Congress will be able to decide whether to fund R&D for the facility in this budget cycle. The winner's prize is \$36 million, which is already requested in DOE's budget for 1994.

#### Vulnerability of basic research

While budgets for major facilities are precarious enough, Happer considers basic research even more "vulnerable." In light of recent expressions in Congress about shifting more R&D funding into so-called strategic research and into generic technologies and manufacturing processes, said Happer, he has become increasingly concerned about support for basic science. "I got into a lot of trouble when I called for academic birth control," Happer observed. "The number of people doubled in condensed matter during the decade of the 1980s and people in it wondered why they faced hardship getting their proposals funded. Research scientists were not being singled out for pain. We tend to think that PhDs are entitled to support by government. That argument is self-centered and self-defeating. Is it any wonder that many of those in Congress think of us as arrogant? We need to rid ourselves of hubris."

Happer then lit out against "people in Washington who think they know everything about technology policy" and argued that "all you have to do is hold off basic research while the money goes to applied research and to work that's closer to the market." He became angry, he said, at a recent

meeting of O'Leary's principal aides to discuss the "values" of DOE. They omitted listing science research and education. "I proposed adding 'science' to the list and, after a brief dialogue, the word was placed at the bottom and a question mark was drawn behind it," Happer noted. "Then I suggested 'education,' and a little later it was added and the word 'training' was written alongside education, again followed by a question mark. I hope this does not represent a new approach to the department's traditional priorities. I tried to convey that tradition by informing the people around the room that DOE and its predecessor agencies had contributed to the research of about 60 Nobel Prize winners."

Happer also was involved in the dispute that broke out in the Administration in April over efforts by Vice President Gore to persuade the President to fulfill the commitment to freezing US levels of CO<sub>2</sub> emissions at 1990 levels by the end of the decade—the year that had been proposed by the European Community for limiting CO<sub>2</sub>. Gore argued that the commitment, promised by Clinton during the 1992 election campaign, would send an unmistakable message to the world that the new Administra-

tion is making a clean break with the Bush Administration's position of refusing to sign the international biodiversity treaty at Rio de Janeiro last summer. Gore's proposal met with resistance from several Cabinet members, principally Treasury Secretary Lloyd Bentsen and DOE's O'Leary. After discussions, O'Leary contended that the Administration had not studied how limiting CO<sub>2</sub> emissions would affect America's energy usage and its industrial economy. In the end, Gore prevailed and Clinton announced on 22 April, Earth Day, that the US would lower emissions of greenhouse gases to 1990 levels by the year 2000—though the details and the regulations or incentives were still to be worked out.

Gore's position, as explained by an aide, is that not joining with the 160 nations that endorsed the Rio agreement would give the impression that scientists still harbored doubts about the threats of global climate change.

"Let's be clear that the decision is political, not scientific," said Happer.

Happer's friends admire his courage and say his experience is a cautionary tale for scientists in government. As SLAC's Drell sees it, "Will is going to be a hard act to follow."

—IRWIN GOODWIN

maturity (see PHYSICS TODAY, May 1987, page S1). In the Soviet Union Evgenii Velikhov and Andrei Sakharov, among others, were publicly critical of the concept.

After reviewing the program during his first four months in the Pentagon, Aspin told reporters he had concluded that the US is still decades away from developing and deploying a space-based defense against missile attacks. The program will now revert to its pre SDI name of Ballistic Missile Defense and seek to improve ground-based systems such as the Patriot missile, which was used in the Persian Gulf War to protect troops against short-range missiles like the Soviet-built Stud.

#### Whacking of the budget

Notwithstanding the change, the program's \$3.8 billion budget request for fiscal 1994 would remain unchanged, said Aspin at his news conference, but future budgets would be downsized to reflect the new course correction. Even so, Aspin has informed some members of Congress that he is willing to accept modest budget cuts sooner as long as R&D is allowed to continue. It is virtually certain that attempts will be made in Congress this summer to whack at least \$1 billion from the program in the quest to cut Pentagon costs and limit the deficit. Scaling back the program, under any name, is bound to cause pain in the defense industries, particularly those located in California, where the state's finance commission estimates that local firms have about one-third of SDI's contracts. Among those most likely to be hard hit are Rockwell International and TRW Space and Electronics Group, which together received contracts totaling \$1 billion last year to develop "Brilliant Eyes," a network of missile-tracking satellites devised by scientists at Lawrence Livermore.

Jobs may be the most potent reason for maintaining the program at any level. Jim Sasser, a Tennessee Democrat who heads the Senate budget committee, has argued for years against SDI's precipitous growth, which, until recent years, has been faster than that of anything else in the budget—"faster than Medicare, Medicaid and even interest on the Federal debt." If the redirection and reduction are seriously carried out, says John Steinbrunner, a defense analyst at the Brookings Institution, "it will help demystify the program. SDI was as much an ideological cause as it was an R&D enterprise to develop a weapons system."

—IRWIN GOODWIN

## ASPIN SHOOTS DOWN 'STAR WARS' FOR DOWN-TO-EARTH DEFENSES

In the Clinton Administration his way, "Star Wars" will be remembered only as a series of movies. On 13 May, Defense Secretary Les Aspin declared "the end of the Star Wars era" and changed the name and direction of the Strategic Defense Initiative, the missile-defense program that President Reagan launched at the end of a televised talk to the nation in March 1983. In fact, Reagan's action had simply repackaged an existing Defense Department program that was running at about \$1 billion per year.

Over the next ten years the US managed to spend some \$32 billion on SDI. With that amount of money it was not surprising that scientists and engineers at the defense labs and at industrial firms came up with such far-out ideas as hypervelocity rockets, particle beams and nuclear-driven x-ray lasers that someday would wage a titanic battle somewhere between heaven and Earth.

Reagan's program didn't achieve his intended goal of "rendering nuclear weapons impotent and obsolete"

and, to be sure, hasn't succeeded in deploying a single weapons system. But it did go some way toward destroying the Soviet system. Alexander Bessmertnykh, the former Soviet foreign minister, said as much during a conference at Princeton last February. The masters of the Kremlin decided that SDI was "something very dangerous" to their military and economic authority, he asserted. Indeed, Bessmertnykh stated the effort to develop an all-Soviet SDI, along with the Chernobyl reactor explosion in 1986, hastened the beginning of the USSR's end.

The idea of shooting down CBMs with space-based lasers and projectiles launched from satellites or platforms met with profound skepticism among many in the scientific community in both countries. The American Physical Society's report on directed-energy weapons, issued in April 1987 by a 14-member committee headed by Nicolaas Bloembergen of Harvard and C. Kumar N. Patel, then with AT&T Bell Labs, found SDI technologies orders of magnitude short of

Clean Water Regs • Environmental Education • Reclamation Awards

SUMMER 1994

# COALVoice

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The Magazine of the National Coal Association

**Political  
Science**



# Is Your Science Eco

**The last decade  
has seen an increase  
in subtle pressure  
upon scientists  
to spin their research to  
support particular  
environmental policies.  
It seems scientific  
examinations are no  
longer evaluated solely  
on the rigor of the  
research, but rather  
on the potential  
political ramifications  
of the conclusions.**



# Logically Correct?

*"The measure of good science is neither the politics of the scientist nor the people with whom the scientist associates. It is the immersion of hypotheses into the acid of truth."*

**W**ITH THIS STATEMENT Ted Koppel ended ABC's "Nightline" episode entitled "Is Science for Sale?" The focus of the program was scientists who have questioned the policy prescriptions of environmentalist leaders.

Koppel's comments seem straightforward enough — there are few scientists who could disagree with him. However, this view is increasingly far from the conventional wisdom being used to formulate environmental policy.

"The demands of environmental and especially health-related regulation... required from science things that it could not deliver," notes Dr. Ronald Gots, author of *Toxic Risks: Science, Regulation and Perception*. Gots and other observers believe there has been subtle pressure upon scientists to modify or spin their research to support particular environmental policies. Scientific examinations are no longer evaluated solely on the carefulness and rigor of the research, but rather on the potential political ramifications of the conclusions. And those whose research fails to conform to preconceived political agendas have their motives and integrity challenged.

Meanwhile, research is cited selectively to support predetermined policy decisions, inconclusive analysis is manipulated to support politically popular causes and dollars are funneled into those areas most likely to produce the desired conclusions. The tentativeness of most scientific research is increasingly subjected to the political pressures of contrasting environmental priorities.

The risk is that as more pressure is placed upon science, its ability to inform environmental policy in a sound manner will deteriorate. "Problems will arise when one will need to depend on scientific judgment," warns Massachusetts Institute of Technology professor Richard Lindzen. If politics is allowed to undermine science, "you leave society with a

resource of some importance diminished." Given the immense complexity of these issues and the increasing costs of regulations, this infusion of "ecological correctness" into the realm of scientific discipline is of grave concern.

## Vice Presidential Appeal

The February 24 "Nightline" illustrated how significant this problem has become. It focused on "anti-environmental" scientists at the request of Vice President Al Gore. "Mr. Gore called to draw our attention to some of the forces — political and economic — behind what he would regard as the anti-environmental movement," Koppel explained. Koppel also noted he had told the vice president that his staff would look at the issue, but also would inform "Nightline" viewers where the information came from. The show proceeded to discuss the purported links between scientists critical of Gore's policies and economic and political interests. Koppel noted critics of the catastrophic global warming theory, such as Dr. S. Fred Singer, Dr. Sherwood Idso and Dr. Patrick Michaels, have received money from the coal and petroleum industries, both of which could be significantly impacted by proposed global warming policies.

However Koppel did not stop there. He also made clear

the scientists at issue also had impressive credentials and were well within the mainstream of their respective disciplines. By the end of the program, there was little doubt that some of Koppel's remarks were directed at the vice president. As

Koppel noted, Gore is "one of the most scientifically literate men to sit in the White House in this century." Therefore, Koppel noted, it is ironic that Gore "is resorting to political means to achieve what should ultimately be resolved on a purely scientific basis."

If Gore is as in tune with scientific developments as a perusal of his best-selling *Earth in the Balance* would suggest, it is strange he should challenge the ability of scientists to arrive at a consensus in the traditional manner. Indeed it seems as if Gore is more concerned with the ecological correctness of ideas than he is with their scientific validity. Is this

BY JONATHAN ADLER

Associate director of environmental studies at the Competitive Enterprise Institute in Washington, D.C.

respect. Gore may be initiating a modern Lysenkoism (see sidebar).

There are many ways to manipulate science for political ends. Perhaps the easiest and most widespread is to discredit those who hold contrasting views. This was no doubt Gore's intent in suggesting this "Nightline" topic to Ted Koppel, and it is an activity that Gore and other environmental leaders have engaged in before. In his book and elsewhere, Gore compared those who discount the need for immediate action on environmental issues to German citizens who ignored the shattering glass of Kristallnacht as the Nazis prepared to go on a genocidal rampage.

### Historic Political Intervention

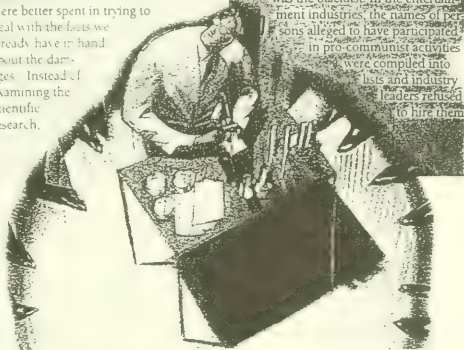
While the vice president may be particularly conspicuous in placing political pressure on science, such activities are in no way exclusive to this administration.

Perhaps one of the most prominent examples of politicized science occurred at the height of former President George Bush's administration. Since the late 1970s some environmentalists had been concerned that sulfur emissions from coal-burning power plants were causing acid deposition that acidified lakes and damaged trees. In the early 1980s, the Environmental Protection Agency (EPA) claimed acid rain was inducing an "aquatic silent spring" and destroying crops and forests. Some scientists, however, were not so sure. To resolve this concern, Congress commissioned the half-billion-dollar National Acid Precipitation Assessment Program (NAPAP), the most extensive environmental study ever conducted.

The NAPAP study would take years to complete. In the meantime, environmentalists and their Congressional allies were hard at work drafting legislation to reduce sulfur emissions to address the presumed acid rain problem. By the time the final report was ready for release, Congress was already on the verge of passing the 1990 Clean Air Act Amendments, complete with multi-billion dollar acid rain control provisions—provisions NAPAP deter-

mined were largely unnecessary. NAPAP concluded "there's no evidence of a general or unusual decline of forests in the United States and Canada due to acid rain" and that a reduction in sulfur emissions only would have, at most, a marginal impact on lake acidity.

While NAPAP downplayed the environmental impact of acid rain, Congress and the Bush administration already had determined an extensive acid rain mitigation program was necessary. As David Hawkins of the Natural Resources Defense Council told "60 Minutes," "we felt [NAPAP] was essentially a misdirection of resources, and that our resources were better spent in trying to deal with the facts we already have in hand about the damages. Instead of examining the scientific research,



Hawkins said the environmental community was "working on trying to get legislation in Washington." When the final NAPAP report was presented to Congress, it received a one hour subcommittee hearing in the Senate, and was never even discussed in the House of Representatives.

Yet the NAPAP story did not end with the enactment of a \$5-\$8 billion annual program that the best science said was largely unnecessary. "60 Minutes" also interviewed noted soil scientist Edward Krug, a scientific advisor to both NAPAP and the EPA. In Krug's view, "the acid rain problem is

### ENVIRONMENTAL BLA

Forty years ago a U.S. senator was so successful at manipulating the news media to discredit those he opposed that the technique came to be called in his name McCarthyism. His tools were half-truth, suggestion, scare, insinuation and innuendo.

McCarthyism wrecked careers and lives including, ultimately, those of its creator, Joseph McCarthy.

Another feature of the McCarthy Era was the blacklist. In the entertainment industries, the names of persons alleged to have participated in pro-communist activities were compiled and into lists and industry leaders refused to hire them.

so small it's hard to see." This was not something the Bush administration's EPA wanted to hear. Assistant Administrator William Rosenberg fired off an angry letter to "60 Minutes" charging Krug had only "limited scientific credibility even in the limited area of surface water acidification."

"My career as a research scientist was jeopardized following my remarks," Krug recalls. The EPA later issued an apology—after Krug threatened to sue the EPA for defamation—but the damage was done. In Krug's mind, he was the victim of "scientific McCarthyism" (see sidebar).

## KLINGING BEING GREENLISTED

BY JENNIFER O'DONNELL

Today, many businesses and industries suspect they may be subject to a later-day form of blacklisting—a reverse form that might be called “greenlisting.”

With a greenlist, firms not specifically listed as environmentally conscious may be perceived as enemies of the environment in the eyes of consumers, even though they satisfy all applicable federal and state regulations.

If a company is rated poorly, the public usually takes action. For example, when The Council on Economic Priorities (CEP) gave General Motors a poor rating, the automobile company received 3,000 telephone calls and 20,000 letters from angry citizens.

And public opinion research found that these negative ratings do more than simply bruise corporate ego; they can

often affect the bottom line.

A recent study by the McLean, Va.-based Wirthlin Group reported 30 percent of the respondents indicated that good “corporate citizenship”—the relationship between a company and society—has a lot of influence on purchasing power. Another 30 percent indicated it had some influence. Only 13 percent said a good public image had no influence at all on their buying power. In a similar study, the CEP asked readers of their shopping guidebook, *Shopping for a Better World*, if they would change brand names or products if a company was given a bad rating. Four out of five readers said they would.

What makes a company a good corporate citizen? Another Wirthlin research reveals 44 percent of respon-

dents said they expect companies to preserve the environment and 19 percent said helping the environment is one way a corporation can have the greatest positive impact on society.

Companies are affected in another way, too. When the DuPont Corporation topped the list of America's Least Cleanest Corporations conducted by the CEP, company officials say it was the toughest not on the bottom line, but on employee morale. “It's especially difficult for employees whose career is dedicated to reducing emissions or finding new ways to eliminate pollution,” explains DuPont's Mary Kate McDonald.

Jennifer O'Donnell is a freelance writer in Chicago.

## Funding for Results

As political considerations have impacted the presentation of science, so too have they impacted scientific research, particularly scientific funding. Increasingly, those projects are funded that support particular political agendas, while others are not. Regulatory agencies have an incentive to fund research that will demonstrate the need for regulatory programs. “It's easier to get funding if you can show evidence of impending climate disasters,” noted one NASA official. For instance, it is unlikely Utah State University would have received \$500,000 from the EPA to analyze methane emissions from bovine flatulence were global warming not a pressing political concern. Indeed, without fears of a human-induced greenhouse world—and other apocalyptic threats—EPA's budget might not be as large as it is today.

Time and time again this means researchers are encouraged to find evidence of environmental problems requiring rapid government attention,

while they are discouraged from suggesting a problem may not exist. In the case of acid rain or global warming, the EPA is not likely to solicit research from scientists that are not already sympathetic. Or, perhaps worse, regulatory agencies may commission such research, but then bury it if it does not reach politically acceptable conclusions. Research on the impact of ethanol on the emission of greenhouse gases was reportedly suppressed when the conclusions failed to support a proposed EPA regulation designed to encourage ethanol's use. This short-circuits the scientific process by restricting the information available for scientists to examine and evaluate.

Moreover, sound environmental policy can hardly be made if policymakers are acting on the basis of incomplete and one-sided information.

## Media Encourages Hypo Science

This tendency to encourage only science which meets a predetermined

environmental litmus test is encouraged by the media. Just as regulatory agencies rely on predictions of gloom and doom to justify expanding regulatory budgets, newspapers and television programs thrive from hyping flawed studies that profess to demonstrate threats to human health and the environment. Promising to expose a sinister ecological threat to infants and children is a far more effective means of attracting viewers than suggesting there is little reason for concern.

Consider the press treatment of recent studies on possible links between industrial chemicals and cancer. On April 13 a front-page headline in *The New York Times* screamed “L1 Breast Cancer Is Possibly Linked to Chemical Sites—Study Finds Higher Risk.” The lengthy article detailed the preliminary results of a non-peer-reviewed study purporting to find a connection between industrial facilities and higher rates of breast cancer. Several days later another study was released, a peer-reviewed analysis of

cancer rates and a potential link to pesticides published in the prestigious *Journal of the National Cancer Institute*. It could find no link between pesticides and cancer rates. This study was the most comprehensive of its kind and yet it received minimal coverage.

Although both studies should be viewed as tentative, it is interesting the study that had undergone a more thorough scientific review was apparently less-suited for prominent display due to its less ecologically correct findings. Cancer is not the number one killer in America, but network evening newscasts carried more stories on cancer in 1993 than any other health problem, including heart disease and AIDS. It is apparently more ecologically correct to allege an environmentally induced cancer epidemic than to focus on the greatest threats to human health.

**Some sources may be more reliable than others, but one cannot assume that a particular scientific opinion is incorrect merely because of where it comes from.**

The media further participates in the push for ecologically correct science in its choice of stories and experts. According to S. Robert Lichter of the Center for Media and Public Affairs, the potential environmental causes of cancer stressed by experts are very different from those covered in the media.

In a survey of members of the American Association for Cancer Research, Lichter found two-thirds of cancer experts believe there are thresholds for carcinogens. This means substances that cause cancer at high doses can be harmless at small doses. However, two-thirds of the experts cited in major media stories held the opposite view. Lichter's research also found "many 'expert' sources who show up frequently in the news are not highly regarded by the scientific community." Moreover, these "experts" tend to play up environmental threats

when quoted by the press. Not only is the media presenting lopsided and inaccurate information on environmental issues, but they also are sending a clear signal to the scientific community: If you want to get quoted in the press, ensure you voice ecologically correct opinions.

### Perceiving the Debate

Part of this tilt may result from the conventional perception of environmental debates. On one side are the kindhearted defenders of the public interest — the environmentalists and concerned scientists. On the other side are industrialists and greedy corporations more concerned with profits than public health. In this morality play, anyone who suggests environmental threats are overblown is immediately suspect. "For the past decade, those of

us in the scientific community who, after a thorough scientific evaluation, designate a consumer product 'safe,' or dismiss charges an environmental chemical poses a human

health hazard, stand accused of the charge that we are 'hired guns' for industry," writes Dr. Elizabeth Whelan, president of the American Council on Science and Health (see profile, page 38).

In a scene reminiscent of James McCarthy in the 1950s, skeptical researchers and experts are questioned about their ties to politically unpopular elements: "Do you now, or have you ever, received funding from the petroleum industry? The coal industry?" Climate experts such as Robert Balling Jr. of Arizona State University were labeled corporate "mouthpieces" for advising a coal industry-sponsored informational campaign about global warming. Balling downplays the impact of these attacks on his professional career as a climate scientist. However, he notes, "I would not want to go out as a 25, 26-year-old Ph.D. and be seen as challenging the global

warming theory."

Public interest groups critical of environmental policy are regularly identified as "industry-funded" organizations, as if the source of funding is the sole determinant of scientific credibility. Scientists such as Singer, Michaels and others have had their work challenged, not because of sloppy methodology, but because of whom they have accepted research funding at one time or another. Others, such as the University of California at Berkeley's Bruce Ames opt to deny any grants from industry sources just to be sure that their research cannot be questioned on anything other than scientific grounds.

This often places scientists in a difficult position, particularly in fields where much of the research is supported by industry in some form. "Industry is discredited automatically," according to science writer Charles Mann, co-author of the forthcoming *Noah's Choice* which examines biodiversity and endangered species, yet industry often funds some of the best research. Forestry research, for example, is heavily supported by the timber industry. Some of the nation's most respected forestry programs, such as that at the University of Washington, have relied upon corporate grants for their existence. When their research produces ecologically incorrect findings, the source of funding is used to discredit the research. This is unwarranted, according to Mann. After all, "just because they have an interest doesn't mean they're wrong." Environmental lobbying organizations "have just as many vested interests and are often just as wrong."

This "intense politicization" of science, in Mann's words, places science "in a position it shouldn't be in." It is hard for those concerned with understanding the environment to support the position that flawed or tainted research is worse than none at all, yet this could be the result if all scientific research with suspect funding were discarded.

Of course funding can affect research. So can a myriad of other fac-

## THE SOVIET EXPERIENCE WITH SCIENCE CONTROL

To truly appreciate how political manipulation can undermine scientific institutions, it is helpful to consider the experience of the Soviet Union.

For years, scientific principles were forcibly subverted by Communist Party doctrine. Science, like all societal institutions, was to serve the cause of enhancing the Soviet state. The resulting pressures upon scientists to research priorities and the inquiry necessary for scientific advancement were debilitating. The phenomenon was referred to as "Lysenkoism."

Lysenkoism takes its name from Trofim Denisovich Lysenko (1898-1976), an agronomist who rose to prominence in the 1930s when he won the favor of Soviet dictator Josef Stalin by proclaiming the need for suitably Communist scientific theories. Lysenko argued the "rules of science" need to be as supportive of the proletarian revolution as the workers in the countryside, and Lysenko promised to deliver.

Lysenkoism required scientific inquiry be molded to ideological preconceptions. It struck at the core of scientific tradition and its emphasis on untrammeled inquiry and rigorous examination of hypotheses irrespective of their practical import. Its influence permeated the whole of Soviet science, hobbling research for decades. Scientists received stiffer or softer treatment based on whether they accepted and publicly endorsed his theories. Many leading scientists were stripped of their posts and some were arrested and exiled to Siberia for biological views too far out of step with Soviet doctrine.

For example, the discussion or examination of conventional genetic theory was prohibited. To acknowledge the potential impact of heredity on human traits would, in Lysenko's view, have undermined the Marxist belief in the perfectibility of humankind through the evolution of societal institutions. Therefore those engaged in genetic research were forced to abandon their work. —JA

tors, including ideological concerns, professional expectations, personal preconceptions and, yes, political pressures. But these factors alone do not determine scientific outcomes. An important element of science is the focus on the methods used and whether or not a given set of data justifies a given set of conclusions, irrespective of the source. Some sources may be more reliable than others, but one cannot assume that a particular scientific opinion is incorrect merely because of where it comes from.

The tobacco industry, for instance, is notorious for denying the overwhelming evidence that smoking causes lung cancer. This is certainly reason to look askance at industry claims. But a growing number of experts now are recognizing the tobacco industry's claims about second-hand smoke — and their critique of the EPA report which purports to show it is a cancer hazard — may well be valid. The studies the tobacco companies point to have been published in peer-reviewed journals while the EPA analysis departed from

generally accepted scientific and statistical norms. It seems, when conventional scientific methods did not produce the desired results, the EPA changed the rules. If second-hand smoke is as dangerous as the EPA claims, why did the EPA resort to what *Science* magazine termed "fancy statistical footwork" in order to prove it. Jacob Sullum, while managing editor of *Reason* magazine, went further, saying, "The contrivances employed by the EPA... indicate that the agency was determined to reach the conclusion that [second-hand smoke] kills non-smokers." Sullum and others are now concerned the EPA will apply this approach to other, less-politically unpopular, substances as a pretense for greater regulation. Indeed, the methodology that indicted second-hand smoke could be used to indict the chlorination of water and the electro-magnetic fields given off by powerlines and household appliances.

### Science Uncorrupted

*"There is nothing new about major institutions seeking to influence science to their own ends, but it has always been a corrupting influence."*

— Ted Koppel, "Nightline"

The environmental issues of concern today are immensely complex. It is essential to rely upon science to fully understand environmental problems and to inform the development of the appropriate policy responses.

Politicizing science and perverting scientific inquiry so as to reinforce preconceived notions about the environment, undermines the ability of societal institutions to address these problems in a responsible and effective manner.

Science does not always yield the desired results, nor does it always produce rapid and definitive answers. But science is the most important tool for understanding the natural world and the human impact upon it. It should not be crippled by politics. ♦

Mr. ROHRABACHER. Does someone else have a specific example that they would like to put on the record?

The CHAIRMAN. We would be pleased to receive any specifics for the record that you could provide on that.

Dr. Graham.

Mr. GRAHAM. Just a comment on the paradox you mentioned that our air is cleaner than ever before, that everybody thinks that it is dirtier. At the speech I mentioned earlier that Bill Reilly, the former EPA administrator, gave at Harvard, he commented that his theory for this is that the Republicans don't publicize this information because they don't want to let the Democrats take any credit for any of those clean air programs and the Democrats don't publicize this information because somebody might draw a conclusion that maybe we have conquered this problem and we ought to get on to the next one, so there is a conspiracy of politics to prevent this getting out.

Mr. ROHRABACHER. Well, that's a fascinating theory.

You had one thing, Mr. Kazman.

Mr. KAZMAN. If I could just comment on this notion, the late scholar Aaron Wildovski at the University of California, who wrote widely on how different cultures approach risk, commented on the irony that here we are, the wealthiest, healthiest country in the history of the world, and yet we are literally scared to death of the air, the water, the food, and that in a sense is a great irony, and one thing we should really consider is the extent to which we are going through the regulatory equivalent of a sort of madness.

We have attached to our testimony a wonderful article called "Witches, Floods, And Wonder Drugs," which discusses the fact that centuries ago we used to accuse people of being witches. We would put them to one test and they wouldn't confess, so we would put them to another test, an ordeal by fire instead of water; they might not confess; until finally one test forced them into confession. Today we don't torture people, we torture data, and if one set of tests on data does not show carcinogenicity we go to another test, we go to another parts per trillion versus parts per billion. If feeding a mouse certain chemicals does not show carcinogenicity then we force feed them, we double the dosage, until finally the data yield the answer that we—one suspects they were looking for all along, namely that here yet is another toxin.

The CHAIRMAN. The time of the gentleman has expired.

Mr. ROHRABACHER. Thank you very much, Mr. Chairman.

The CHAIRMAN. Mr. Gutknecht.

Mr. GUTKNECHT. No questions.

The CHAIRMAN. Mr. Gutknecht has no questions.

Mr. Olver.

Mr. OLVER. Thank you, Mr. Chairman.

I, too, apologize for not being here earlier. Another committee I sit on was sitting at exactly the same time.

I have a couple of questions, if I can keep them short so that you can answer shortly, because the time each of us is allotted is quite short.

Dr. Graham, you are a supporter of this legislation, as I understand it, basically, not specifically, that you support it in its totality, but I read that from your testimony. In your testimony you

have criticized some agencies that—and I am quoting this at least—that have neglected to assess the impact of hazards on highly exposed or susceptible subpopulations of citizens, end quote.

Would you support adding some sort of language that would specifically state that one principle of good risk assessment is risk characterizations for those subpopulations or for sensitive subpopulations?

Mr. GRAHAM. The way I read the current legislation is that it does require that you characterize the risk not only for the population as a whole but for specific populations, and we can share and look at the exact language.

But I can assure you that if we are talking about doing risk analysis based upon the best available science, the risk analysis community is going to make sure that we make sure that the sensitive populations, whether they be asthmatics, whether they be people who are genetically sensitive in some way, that at least we generate whatever information we have on their health and safety and not just focus on the average American.

Mr. OLVER. All right. I would like to explore that maybe individually between us a bit.

Mr. GRAHAM. Sure.

Mr. OLVER. That point.

The bill basically places a good deal of emphasis on the use of scientifically objective and unbiased data. Now this would require the use of scientific models in which there is already a certain amount of controversy. The bill requires the use of scientific models based on science—scientific data, but also talks about economic models in which the degree of agreement is far greater—disagreement is far greater, and in fact very often it is almost impossible to confirm the results because all you can do is look afterward at end results after the fact and then look at statistical analyses of what really—what was really going on there, so a lot of different things are confounded in the data.

Now what then do you mean—what do we mean by unbiased data to reach those kinds of decisions when you are mixing scientific and economic models?

Mr. GRAHAM. Well, both the scientific models and the economic models often suffer from the same problem, which is that we are not able to validate, know for sure whether or not the prediction of the model in fact proved to be correct.

Mr. OLVER. The scientific and economic models—

Mr. GRAHAM. They have the same problem.

Mr. OLVER. To the same degree, would you say?

Mr. GRAHAM. It depends on the issue. When we test rodents at 5,000 parts per million in order to figure out what the risks to people are one part per billion and we extrapolate down all those orders of magnitude, let me assure you, we have a validation problem as bad as the macroeconomic modelers have. So we have got problems on both.

But the short answer is, I think it is good. The legislation asks the economists to get peer reviewed as well as the other scientists in the community. I think that is a very constructive move.

Mr. OLVER. You are working on a course—I was interested in this in your testimony—you give a course at the Harvard School of

Public Health where the basic principle is that Government should provide risk protection to citizens if those who benefit would judge themselves better off even if they incurred the costs of providing the risk protection.

Now I want to explore a couple of things. Earlier in the testimony you have a paragraph about lead in gasoline which I think states that even though this was not driven by opinion, public opinion, by demand from people who might be helped or media campaigns or even environmental advocacy groups, that it was driven by a careful cost-benefit analysis of the issue, which I think suggests that you thought that that was very valuable to have done.

Now what about lead in—to take a different—lead paint in housing and so forth? How would one apply the principles of your course there, since the beneficiaries are largely children who probably don't know either much about the judgment that their—their betterment in this process and surely are not in a position to be able to make that decision on payment for it according to the principles of your course and good risk analysis.

Mr. GRAHAM. Yes. I have a student named Joshua Cohen who just finished a doctoral dissertation on what the optimal strategies would be to prevent childhood lead poisoning from kids ingesting house dust contaminated with lead paint, and he concludes, based upon interviews with their parents, that many of these parents would be willing to pay significant amounts of money to reduce the probability that their children would be in that situation.

Mr. OLVER. Certainly if their children—certainly the parents who have had any child who has suffered from elevated lead.

Mr. GRAHAM. And even those who don't. If they felt the risk was significant to their children, even if they hadn't experienced it yet, would be willing to pay some amounts.

But what he finds is that the cost of removing the lead from these homes is oftentimes so substantial that really only in about somewhere between 1 and 5 percent of the total homes where there is lead paint in the home would it really be worthwhile to go after this.

So I think cost-benefit analysis can give you a lot of insight into when it is a useful strategy to go after some of these environmental problems, and in some cases it supports a lot of regulation and a lot of Government action, and in some cases it doesn't support much.

Mr. OLVER. So what do you do then with the huge amounts of housing—

The CHAIRMAN. The time of the gentleman has expired.

The gentleman from the State of California, Mr. Baker.

Mr. BAKER. Thank you very much, and I hate to disagree with my distinguished colleague, Mr. Ehlers, next to me who is a scientist, but I don't want you to feel guilty because you are not perfect. Those of us who believe in a higher being know that we are not going to reach perfection on this Earth, so we don't expect you to be perfect, but what we expect is the balance of nature that has been lacking the last two decades. This socialist or overbearing Government has said to the public, "We are going to make this life risk free, and we don't care how many levels of Government we

bankrupt to do it," and so we have passed these laws without regard to cost or risk assessment.

So we are coming to you, who have toiled so well in the darkness these last two decades, to say come out into center stage, turn the spotlight on, and give us some relevant facts from which we can make intelligent decisions. That is all we are asking. So I want to compliment you for doing it and for being available with something other than political rhetoric, and so please don't apologize for not being perfect. None of us are, and you are going to add a lot.

Let me give you a couple of examples. In the 1970's Dow Chemical wanted to build a chemical plant in California in the Bay Area where we desperately needed it and when there was an infrastructure of chemical plants around there to do it. They only had to complete a hurdle of 40 regulations. After two years and \$10 million in legal fees, they had two of the 40 permits. They gave up, the manager of the project died of a broken heart, and the project went to Canada, the most environmentally sensitive nation on our continent, who in six months not only approved the permits but built the plant. There was no one like you folks around to say this is absurd.

Number two, we have scared the public to death, as you have mentioned, and I can mention the cyclamate scare where we took \$28,000 worth of canned fruit and threw it away, later finding out that you would have had to drink, what, 600—the equivalent of 600 Cokes a day or 10 tons of canned pears in order to ever get cancer. But that was too late for the amount of food that we could have given to the Third World or given to our poor; we threw it away. Alar, apples, Red Dye No. 2, nuclear power. We have consistently allowed people to scare each other to death, and that holds back progress. Think what we could do to air pollution if we had a scientifically driven nuclear power program.

Three, in my district there was a tractor man who sold tractors. Well, he was in his late eighties. In the old days it was quite acceptable to wash down the tractor with solvents and to spill the gas on the ground, but today, now that we can measure in the 10 billionths part per minute, or second per being, we have found that we have, guess what, gasoline and solvents in the ground. So they said, "Dig it up," which he did, and he stacked it up.

Now best available technology would allow him on a lightly breezy day to air farm that. There would be a little addition to air pollution, and it would be gone. Can't do that. Haul it to Bakersfield. Haul all that dirt to a site class one dump, store it at Bakersfield, as if that gets rid of the problem. Cost, one million. So instead of using best available technology, we have that dirt stacked on its original site under plastic 10 years later because nobody has \$1 million to move it and move the problem rather than cure the problem.

So you really—I want to thank you for being part of the solution. We will make the political solutions, how much are we willing to expend to correct a known problem, if you can give us the facts. So I want to say thank you.

And in California let me just aim you towards one more, and that is the famous FIP, the Federal Implementation Plan, in air pollution. We have set the air pollution standards so high that they

are unattainable, and the State is struggling to reach attainment by having a State-run plan. Unfortunately, we are now in court tied up so the State-run plan can't be approved by the EPA. The EPA is going to mandate the FIP, and we are going to have more economic disaster in California when all of us want to improve air pollution.

In the Bay Area we are dangerously close to reaching attainment. Do you know what that means in Federal Government circles? If your area reaches air pollution attainment—in other words, you are no longer a danger—we cut off your Federal funding. So there is a reverse incentive and we are fighting now to keep pollution in the Bay Area so we can maintain our hooks into the Federal Treasury and transportation funds. But the Federally implemented FIP, instead of being reasonable, is totally unreasonable and everyone, including the EPA director and the director of transportation, admit it, but because there wasn't a group of risk assessment people around to give us alternatives and give us reality, we continue to march along on in this, okay, we'll let the enviros take us to court, and we will spend any untold amount of Federal dollars in order to chase these unattainable goals.

So I want to thank you for being here and for providing the balance that we need, because there is nobody on this panel, Democrat or Republican, that wants to enhance pollution or wants to make this world less safe for future generations, but we have got to admit to the world we can't make it totally, absolutely safe.

The CHAIRMAN. The time of the gentleman has expired.

Mr. BAKER. The sermon is over anyway, sir.

The CHAIRMAN. The gentleman from Oklahoma, Mr. Largent, whom we congratulate for your election to the Hall of Fame within the last few days—

Mr. LARGENT. Thank you, Mr. Chairman.

The CHAIRMAN. —and wonder if they ever gave you any risk assessment before they sent you in against 300-pound linemen.

[Laughter.]

The gentleman is recognized.

Mr. LARGENT. They also did a cost-benefit analysis. The benefits were greater than the costs.

Mr. Garner, I share your concerns about creating another layer of bureaucracy, another problem with the Government in terms of risk assessment. Do you have any recommendations as to how we avoid that?

Mr. GARNER. Well, I think the key thing is that what you are trying to do is to hit a balance point of making sure that you get accurate and good information from the agencies that are putting forward legislation or regulations, that they have a burden to give you good information, that that is subject to some kind of peer review so that outsiders and interested parties can comment on it and you can—to make sure you are getting good information.

If you raise the importance of the risk assessments too much, I fear that you do make it become just another layer of obstacles to getting anything done, and that is to be prevented, I think, by not making it subject to judicial review except in very limited circumstances, by not overdoing the requirements. I think you mentioned, if it is a little impact, you know, a little analysis, and if it

is a big impact, a big analysis, just trying to keep some common sense into how you go about this.

I think the bill as drafted is fairly reasonable, but I think you watch it and see how it works, and if it doesn't work the way you think it should, you go back and you fix it.

Mr. LARGENT. Well, I agree with you too, and sometimes common sense isn't very common. Well, I appreciate your comments.

I think that, you know, politics in itself is not an exact science, but the one thing that, in my limited experience here in Washington, D.C., that one law that keeps sort of raising--rearing its ugly head is the law of unintended consequences, and we need to figure out a way to avoid that.

Mr. GARNER. One more thing I would encourage is that the Environmental Protection Agency, some parts of it, has more and more made efforts to pull together the impacted parties, to talk about things before they do it, and there was a period of time when they didn't do that, the regulated community, their doors were shut, they wouldn't talk to you. That would sort of contaminate the process.

Now in some areas they are bringing all the parties to the table where you can sit in the same room and you have the industry, the Government people, the environmental groups, and you sit down and you try to work your way through things. I think that is to be encouraged. I think there are a lot of things that we do that, if you put people together and say, well, let's see if we can reach consensus on this instead of sitting listening to the extreme points of view have at each other all the time, a lot of times we can come up with the common sense solutions.

The CHAIRMAN. Thank you.

Mr. Doggett.

Mr. DOGGETT. Thank you, Mr. Chairman.

I would have to say that in the spirit of true bipartisanship, that I would have to agree wholeheartedly with Mr. Baker's point that our colleagues in the majority are not perfect. I think that this bill is not either and would ask Dr. Graham specifically, it has been suggested by some people who are active in this field that there's still plenty of shabby practices in the conducting of risk assessments. By rushing to impose this requirement on so many agencies in such a broad way, are we going to have the probability that we will have, along with some good work, a significant number of studies that are conducted by essentially amateurs that form the basis of regulations that will affect the health and safety of millions of Americans?

Mr. GRAHAM. Yes, it is a good question, what is the quality control on the risk analysts in this business, and I think it is a very fair question, and the first thing I would say is, the authors of this bill are very sensitive about that.

There is a very strong section in this bill that requires that there be peer review by qualified experts of what the agency risk analysts are actually doing in these studies, and some people call that bureaucracy, they say that is more layers of bureaucracy. I mean I think it is actually a reasonable thing to say, that if we are going to have estimates made of danger from lead poisoning to children,

for example, that we do it based upon the best available science and that we have peer review requirements on that.

So I see the point you are making, but at the same time I see that the authors of the legislation are concerned about not giving too much power to a very immature and developing science, and that is why those peer review requirements are in there.

I do like the suggestion of finding a way to make the peer review a little bit more independent of the agencies themselves. I think that was quite a constructive point, though I might pick the Office of Science and Technology Policy rather than the Office of Management and Budget just because I feel like they may be a little bit better able to carry out that function.

Mr. DOGGETT. You have also mentioned in response there this term "bureaucracy," and we are adding some additional layers in the process of course of rule-making, and I have some concern about what the actual cost of that will be. I know that EPA, for example, has said that it would expand from 38 to 200—I guess to 2,800 of these studies a year. I saw one recently that goes on, I guess, into the thousands of pages of the type that they do already. I expect that it is going to take a few employees to do that. EPA estimate \$220 million a year in additional expenditures, and I am wondering if there has been any type of cost-benefit assessment of adding all of these additional employees to do these additional cost-benefit studies.

Mr. GRAHAM. Let's think about the numbers you just talked about for a minute: \$220 million. Let's start, for the sake of argument, and say that is absolutely correct. The Environmental Protection Agency, it holds roughly a \$5 billion agency in taxpayer costs, yet it imposes on the private sector of the economy and the States and localities \$150 billion per year for every dollar of EPA taxpayer costs. That is \$30 in external activity. Even if we were to inadvertently double the size of EPA, if we could reduce by 10 percent the \$150 billion cost of EPA, it would save \$15 billion and only cost an extra \$5 billion.

So when you are talking in millions of dollars, you are in the noise level on this issue. This is a massive, massive regulatory program on the States and localities and the economy of this country. We can afford to do a little risk analysis to figure out how to save some of that \$150 billion. That is where my perspective comes from.

Mr. DOGGETT. Have you made any analysis of how much of an expansion it will be necessary in EPA and other agencies in order to accomplish this, and do you—you use the term "doubling the size" of EPA. Do you favor an expansion of EPA to do this?

Mr. GRAHAM. No. What I was saying is, even if you take the worst case possibility as the agencies might be inclined to do, and say—suppose it had to double the size of EPA. That would cost the country five billion more dollars to do that, and yet if you could just reduce by 10 percent the private sector burden you save \$15 billion, so I think we ought to get, and I think the idea of getting the Congressional Research—Budget Office, for example, to make some estimates of this is fine, but in the process of doing that I certainly hope they will look at the possibility of actually rearranging some of the existing personnel in EPA, reducing, for example, the num-

ber of lawyers at the U.S. Environmental Protection Agency and having a few more of them invested in risk analysis, and maybe we can do this without a substantial increase in the overall size of the Environmental Protection Agency.

Mr. DOGGETT. You have not seen any estimate on how much of an expansion or whether this could be done?

Mr. GRAHAM. I haven't, no. I suspect you will certainly hear that from the agencies when they testify.

Mr. DOGGETT. Mr. Chairman, I would also ask that some documents prepared by the minority staff, one entitled "Myth That Environmental Regulations Cause Job Losses Is Debunked," be made a part of the record.

The CHAIRMAN. Without objection.

Mr. DOGGETT. Thank you.

[The documents follow:]

## Myth That Environmental Regulations Cause Job Loss is Debunked

■ **Study reveals the number of layoffs and plant closures is actually small and that regulations have a small positive effect**

Conventional wisdom says that environmental regulations cost jobs. But a new study by the Washington, D.C.-based Economic Policy Institute says that conventional wisdom is wrong. Two decades of research into the relationship between jobs and environmental protection actually reveals that the number of layoffs and plant closures caused by regulations has been surprisingly small.

The main point of the study—and all economists agree—is that at the national level, there is no trade-off between jobs and environmental protection. At the local level, when you look at the data, actual layoffs that result from environmental and safety regulations have been quite small—on the order of 1,000 to 2,000 a year,” says study author Eban B. Goodstein, an economics professor at Skidmore College, Saratoga Springs, N.Y.

In fact, Goodstein's research shows that the vast majority of economywide—or national-level—studies indicates that environmental regulation has a small positive effect on overall employment. This is so because environmental protection requires the intensive use of labor or domestically produced materials in such projects as recycling and construction of sewage facilities.

The jobs created by environmental regulation are heavily weighted to blue-collar sectors, not government- or private-service sectors. In 1991, 57% of jobs generated by environmental spending were in communications, manufacturing, transportation, and utilities; only 22% of all nonfarm jobs were in these

sectors. And despite the charge that environmental regulation only creates jobs for government bureaucrats, government jobs accounted for just 11% of environmentally related employment compared with 17% economywide.

Using Labor Department data from 1987 through 1990, Goodstein found that only four plants per year were shut down because of environmental or safety regulations. This translates to less than 0.1% of all large-scale layoffs.

As an example of how prediction overstates reality, Goodstein cites a 1990 study done by the Business Roundtable in Washington, D.C.-based association chief executive officers. That study attempted to predict job losses from regulations likely to be promulgated under the Clean Air Act of 1990.

During debate over renewal of the clean air law, many people expressed concern over the possible economic consequences of tendered amendments. Concern about potential job losses was so high that legislators eventually included a provision in the 1990 Clean Air Act amendments allocating \$50 million per year for job retraining funds.

The Business Roundtable study predicted that a minimum of 200,000 jobs and possibly as many as 1 million to 2 million jobs would be wiped out. The reality, Goodstein tells C&EN, “is that by June 1991 only 2,363 jobs had been lost because of Clean Air Act regulations.”

Johanna Schneider, director of communications for the Business Roundtable, points out that the study's “predictions of job loss were based on the Clean Air

### Environmental protection is not key reason for mass layoffs

	1987		1988		1989		1990	
	Layoff events	Job loss	Layoff events	Job loss	Layoff events	Job loss	Layoff events	Job loss
Automation	9	951	7	737	11	1,378	11	1,688
Bankruptcy	43	7,259	76	16,559	81	18,599	100	26,428
Business ownership change	88	30,955	92	18,973	82	19,147	78	16,989
Contract completion	147	27,696	178	50,822	225	50,971	201	40,167
Domestic relocation	49	10,877	68	12,816	68	1,138	114	18,512
Environment related*	4	511	4	388	5	1,304	4	390
Import competition	40	8,328	34	8,222	43	8,310	69	10,028
Labor-management dispute	43	10,992	26	2,824	47	40,387	na	na
Material shortages	1	161	20	2,169	24	4,216	20	1,000
Model changeover	17	1,154	21	7,186	—	9,089	15	—
Overseas relocation	30	4,963	10	1,225	6	1,189	13	1,100
Seasonal work	516	101,158	710	144,522	889	175,970	884	167,087
Slack work	935	94,071	450	69,764	661	102,607	943	142,038
Other (including reorganization)	240	5,140	229	51,744	255	46,778	284	97,474
Not reported	162	23,826	216	45,764	211	53,604	168	31,784
TOTAL	2,020	408,681	1,322	490,300	2,764	572,570	3,078	586,590
ALL REASONS*								

\* Includes environmental and safety regulations. Source: Department of Labor.

## GOVERNMENT

A "landfill" must initially be created, and as modified by Congress. And she adds, the Clean Air Act of 1990 was not yet even fully implemented.

At the local level, the personal and social costs of job loss and unemployment cannot be minimized, whether they are the result of environmental and safety regulations or more general causes, Goodstein says. But even at the local level, the trade-off between jobs and the environment "is shockingly small when you look at the data," he explains. In fact, more jobs are probably lost because of corporate downsizing, import competition, and defense cutbacks, he adds.

The trade-offs between jobs and environmental protection are most apparent in extractive industries such as mining and logging where local job loss and unemployment can be very significant. But even in these instances, new jobs dependent on a clean environment or providing substitute products for the "locked up" resource are generated elsewhere in the economy. Over time, job gains will generally balance job losses, "though national policy will have to address local problems of dislocation," the study states.

Nor has environmental protection been responsible for the decline of manufacturing jobs in the U.S. because companies have fled to "pollution havens"—countries where environmental regulation is lax. Companies are relocating to less industrialized countries, but primarily because labor costs are low, Goodstein says.

He advocates that immediate steps—

expanded job training and adjustment assistance—be taken to help workers in manufacturing.

Goodstein contends, markets for clean manufacturing and energy technologies will provide the high-wage jolt to the economy that car manufacturing and defense provided in the 1950s and '60s.

"Demand for clean technologies will be the driving force behind industrial job creation," Goodstein says. "Ensuring that U.S. firms develop and maintain the lead in these fields will allow the country to capitalize on high-wage employment opportunities in environmental protection."

John C. Shanahan, environmental policy analyst with the Heritage Foundation, disagreed. "The idea that environmental regulation is good for the economy is absurd. What's ignored in the [Goodstein] study is that the dollars spent on environmental regulation and clean technologies create jobs, technology, and exports—can't be spent where they would be most productive. The free market always gets more economic productivity and economic growth out of every dollar spent than the federal government does."

In short, Shanahan says, "What the study ignores is that whatever productivity is created by environmental regulation is far outweighed by economic activity lost elsewhere."

The Economic Policy Institute study, "Jobs at the Environment: The National Trade-Off," can be obtained from Public Interest Publications by phoning (800) 537-9339; the price is \$1.

—Lisa Finken

## Report notes information superhighway barriers

Republican House Speaker Newt Gingrich of Georgia has recently boosted the already high visibility of the information revolution in his fervent talks about computerized communications that will revolutionize tomorrow's politics. According to Gingrich and futurologist Alvin Toffler, this "third technological wave" (after agriculture and manufacturing technologies) will revolutionize democracy, commerce, and everything else by putting everyone on-line with everyone else, empowering all.

But the new report, "Significant barriers need to be overcome before the miracles of information technology can come to fruition in schools, businesses, medical centers, and homes.

The report was issued late last month by the private, Washington, D.C.-based Council on Competitiveness. The council is a think tank established in 1981 and composed of about 150 leaders from high-tech corporations, universities, and other areas.

A council task force has been studying the so-called National Information Infrastructure (NII), also known as the information superhighway. Its latest report on the subject, "Breaking the Barriers to the National Information Infrastructure," is based on a conference the council sponsored last September.

As the report points out, the hardware that links information to users is there. The always-evolving software that makes

it work is still in its infancy. High costs, human resistance, incompatibility between systems, multitudinous legal hurdles, and privacy concerns.

Paul A. Allaire, chief executive officer of Xerox Corp., which helped generate the information revolution, remains optimistic. "As the National Information Infrastructure grows," he says, "it will have a revolutionary impact on national competitiveness. Those nations that establish this infrastructure and develop a broad range of applications first will have a tremendous competitive advantage over those that lag behind."

But the barriers do exist. Take education. "Schools and application developers both learned that unless NII applications are integrated into the regular curriculum, students cannot realize the full benefits of the new technology," states the report. "They miss the chance to work on projects with students from around the world."

Teachers, too, face barriers. "Most teachers tend to lose interest in new technology quickly if it appears to be a gimmick rather than a real aid to learning."

The council points to some examples where schools successfully integrated technology with teaching. A key practice was establishing a mentoring program in which information-literate teachers personally trained colleagues more skittish about the new tools and techniques.

The report says the one overriding difficulty in establishing a fully operational NII is society's "basic resistance to change." Most organizations are more comfortable with the slowness and deliberateness of paperwork. People in business and the professions are uncomfortable with sharing their information, fearing loss of control of their domains. Few are convinced that the costs of installing the equipment and learning how to use it will outweigh the benefits. Also, extensive legal and regulatory barriers remain to be crossed. Physicians, for example, cannot practice electronically across state lines; their licenses are valid in only one state.

In addition, much of the technology businesses need to interact through networks is incompatible and organizations continue to resist because benefits and costs are difficult to measure. The report cites example after example of barriers and opportunities in manufacturing,

The CHAIRMAN. Mr. Garner.

Mr. GARNER. Just a quick point. One other possibility would be that maybe we could slow down a little bit and prioritize what we are going to do better and not do so much of it. If there are 2,000 risk assessments, that tells me 2,000 things that are coming at us on top of what we have already got. You know, slowing it down a little bit wouldn't be such a bad thing.

Mr. OLVER. Would the gentleman from Texas yield?

Mr. DOGGETT. Surely.

The CHAIRMAN. The time of the gentleman has expired.

The chair recognizes Ms. Jackson Lee.

Ms. JACKSON LEE. Mr. Chairman, thank you very much for recognition, and, to the witnesses, let me offer my appreciation for your presence and my apology for having a committee that was meeting the exact same time but, more importantly, was involved in markup. Otherwise I would have tried to use my roller skates and moved from committee to committee.

I happen to come to the table with, I guess, partly a background which you have acknowledged great respect for as I came in the room, lawyers, an attorney, but certainly I have had the experience of being before the Federal Energy Regulatory Commission as an attorney representing individuals being so regulated, or companies, along with the Food and Drug Administration as well as the Federal Trade Commission, so there is at least that firsthand experience.

I have noted Mr. Brown's comments indicating the acknowledgment that those of us who are new members have not had the benefit of extended hearings on this, and I wish we could because I think there would be an opportunity to forge a bipartisan look at this issue.

I would hope that we would be able to get from all of the cabinet departments and the independent agencies their perspective on H.R. 9 so that there could be certainly some thought as we deliberate further on this particular legislation.

But what I would ask Dr. Graham and whoever else might answer this question, since I may have missed it: Do you not have any favorables to say about prior regulations as it relates to some of the dangers that have been prevented because of the regulation of some of the agencies, i.e., nuclear plant licensing and child immunization programs, the fact that we now indicate on cigarettes that they are hazardous for your health, and I think that there would be few of good reason and good mind that would challenge that, and I'm sure I could find one or two, but in any event that there is value to some form of regulation that has preceded us, all recognizing of course that we want to do it in a rational and balanced manner.

The second half of my question is, how would this seemingly massive risk assessment approach impact, for example, an M.D. Anderson in my community and, for example, a NASA in my community?

Mr. GRAHAM. First of all, I think the question is excellent on what do we know about the historical experience of our various regulatory agencies on how successful they have been in improving air quality, protecting public health and safety, and my own feeling

is that we have a lot of examples of where there have been successes. I am just checking off a little list here, and the details of this are in my written testimony: The phase-out of lead in gasoline and the protection to children that that has provided, reducing the blood lead levels of lead and the possible neurologic effects. The phase-out of ozone-depleting chemicals. The mandatory requirement that all new cars be produced with air bags not only on the driver's side but also on the passenger's side. We are now at the Harvard Injury Control Center measuring the benefits of that in reduced head injuries among both adults and children. Child restraint use laws that require children to be protected in cars. And in each of these cases we have. I think, well conducted analyses, sometimes by the Federal Government, showing the benefits of these regulations outweigh their costs.

So if anybody believes that this legislation is going to wipe out all health, safety, and environmental regulation, let me assure you, they are in for a big surprise. We are going to find lots of regulations that have benefits that are greater than their costs and that have substantial reductions in risk. What this legislation is aimed at is drawing the distinction between those who do have a strong scientific case and those that do not, and I think that is the value in this kind of legislation and the reason I support it.

Mr. JASINOWSKI. If I could just reinforce that and add one other point about the fact that this proposal is aimed at doing things better, not reducing the amount of appropriate coverage to environmental and safety regulations. I think the private sector believes that we have had enormous benefits from the programs of the last couple of decades, and I can give you dozens of companies that now make more money by producing a cleaner environment and pollution prevention than if they didn't. So the mind set is that this is a very positive historical development. What we are simply saying here is, let's stop wasting money in the process of doing it when we don't have to.

The legislation goes beyond risk assessment and requires prioritization, risk management, and doing some other things that are aimed at eliminating cases where we not only don't miscalculate risk but we waste money in other ways. There are other costs that are not being calculated in the system that are enormous, and this would require a management that brings benefits and costs together in a consistent way.

Ms. JACKSON LEE. My intent would be to certainly—and I appreciate certainly very much the response—my intent would be to certainly carefully study whether that balance is there. I think it is important that you were on the record suggesting that, one, there are certainly valuable—which we all acknowledge—regulations which have enhanced both the economy and the state of health of Americans as well, that that is not what you would prohibit in this legislation.

Let me offer just a moment of caution that in the implementation I worry that some of that may occur only because of seemingly the broad reach, but it is my intent, as I said earlier, to review it further, to seek more information, and to ensure that specific communities and, in particular, research communities, that the Federal

Government impacts can be fully and positively impacted by what this legislation is trying to do.

Thank you, Mr. Chairman.

The CHAIRMAN. The time of the gentlelady has expired.

I thank the committee for their participation and the panel in addition.

I would not want to let one thing stand that was just mentioned by the gentlelady before, that there have been inadequate hearings on this. Over the period of the last couple of years we have done 17 hearings. There will be four hearings done this week on this particular item, two here, two in the Commerce Committee. This legislation is going to be thoroughly examined before we go into markup because we think that it is very, very important to have a good basis on which to make a judgment. This committee last year marked up legislation based upon hearings. I assure her that the hearing record from last year continues to be a part of that which we will continue with in this year.

I thought it was interesting to note, and it answers—it speaks to a question that arose in this committee in an initial hearing where the EPA administrator mentioned that one of the reasons why we needed to be very careful of what we did in risk analysis was because we needed to make certain that things like lead in gasoline did, in fact, have an opportunity to become regulation and save lives. I was interested in, in at least one of your testimony, you mentioned that in particular as being something where it was done properly in the first place and that there was good science behind it. It seems to me that that is part of a case that needs to be made here, and I would appreciate a comment from each of you on that particular issue, and, Dr. Graham, you just raised it a moment ago.

Mr. GRAHAM. Right.

The CHAIRMAN. It seems to me that one of the things that is going to happen here is that we are actually going to get a basis for good regulation out of this kind of approach, it is not just going to be an attempt to obliterate the ability of the Government to regulate in environmental health and safety areas, and I would appreciate your comment.

Mr. GRAHAM. Sure. I think it is a good point.

The history of lead in gasoline is instructive because actually the requirement to phase out and to reduce lead in gasoline was on President Reagan's hit list of regulations that were to be gotten rid of, and it was cost-benefit analysis done within EPA that persuaded people not only at the career level but also President Reagan's key regulatory leaders that, in fact, that regulation should be retained, and eventually, without any pressure from environmental groups, without any national media stories, they actually came to the conclusion it would be better to accelerate the phase-out of lead in gasoline based upon benefit cost analysis, dollars and cents, kids who were retarded, for example, and the costs of caring for them versus the costs in changing the refining of gasoline, and the effects of lead in gasoline on catalytic converters, and the damage it does to the vehicle.

There were lots of industries that did not want to phase out lead in gasoline, yet the analysis showed that in that case that was a

reasonable and appropriate step to take based upon cost-benefit analysis.

So there are going to be a lot of things that are going to be done here based on cost-benefit analysis that are going to be pro-regulation. There are going to be industry people whining around about how they don't like this, okay? Washington is still going to look pretty much like the same town it was, but we are going to be a little bit more selective, we are going to go after targeting where we have a strong case.

The CHAIRMAN. Well, I think that is important because we need to understand that there is some science that is going to drive us toward making rational decisions, that there is appropriate regulation.

On the other hand, what has gone wrong here, it seems to me, comes back to Mr. Kazman's point about the toothpick. If, in fact, he is right that the toothpick causes one death per year in the country, that means that we have a one in 250 million risk of dying as a result of killer toothpicks. My guess is that there are some other people who get hurt by toothpicks in a year, that you might find 250 people who puncture themselves with a toothpick and even draw blood as a result of toothpick punctures, which means that there is about a one in a million chance of being either injured or killed by toothpicks.

Now, you know, my guess is that a one in a million risk of being either injured or killed is right in the area of a lot of what the departments and agencies use to scare the bejeebers out of people about potential risks to their life and health by some other element that is out there without very good scientific data to back it up. Is that, in fact, what we are talking about trying to deal with as a result of getting a better scientific basis for our decision making?

Mr. KAZMAN. It is partly a scientific basis. It is also partly getting the public to realize just what they should be comparing things to. Once again, to shout out, "We have got a toxin here, we have got a carcinogen, we have got hazardous waste," is to scare people, and when their alarm turns into calls for programs that they don't have to fund directly, those programs get all the more steam.

If you can get agencies to start talking about risks in context as opposed to risks in the abstract, to start comparing what they are talking about to the risk of fire, to the risk of a toothpick, it will add quite a bit more common sense to the whole public debate over this.

Mr. GARNER. Translating the risk assessment to the public is very important. They see one in a million as something—well, it's like the lottery. I mean they will spend on those kinds of odds. So the numbers really don't get across what the reality is, and I think that is a challenge for all of us who are dealing with this, to try to make sure that we have legitimate ways to communicate the real risks with the public and have them be part of this dialogue.

The CHAIRMAN. As a matter of fact, the one in a million risk is a pretty good risk in terms of the lottery. I mean you have got a pretty sure shot if you can get it to one in a million in the lotteries that people play regularly, thinking that they are somehow going to get a payoff from them.

Mr. Jasinowski.

Mr. JASINOWSKI. Mr. Chairman, I would just stress again, it has been stressed many times in the testimony, that it is partly the toothpick risk issue being so absurdly low and it is also the extraordinary costs on the other side which have not been fully identified. The taxpayer costs of funding the bureaucracy, \$5 billion in the case of EPA, the cost of what is imposed on the private sector in the environmental area of \$140 billion, and the costs of lost opportunities because of waste. If you add all that up, you are dealing with things that are the size of the medicare program in one case, and if you take all regulations, it is the medicare program and the Defense Department, and this legislation would require systematic comparison of risks and costs and benefits, and I think that that is terribly important.

The CHAIRMAN. Let me get to just a few things. Do I understand correctly that all of you have essentially testified that what this legislation ought to do is set forth principles by which we would make rational risk assessments? Is that generally what I am hearing from all of you, that that is the important factor in what we end up with here?

Mr. JASINOWSKI. Yes, sir.

Mr. GRAHAM. I agree.

The CHAIRMAN. Is there anybody that disagrees with that?

Second, do any of you see any major harm in raising the threshold from the \$25 million which is in the bill to some higher threshold if indeed that would help mitigate some of the potential cost arguments?

Mr. JASINOWSKI. No. In fact, the coalition we are testifying in behalf of, Mr. Chairman, suggested and recommended \$50 million.

The CHAIRMAN. Fifty million?

Mr. JASINOWSKI. Yes, sir.

The CHAIRMAN. Is there anybody else that has any thoughts along that particular line?

I get silence. My guess—am I interpreting that correctly that you don't have any particular problems with this changing the threshold?

Mr. GARNER. I think it is a good idea.

The CHAIRMAN. I did notice some division among the panel on the issue of judicial review. Mr. Garner thinks that judicial review is not something that we ought to pursue in this bill. I gathered that the rest of you believed that it should be included in some form in the bill. Is my interpretation of your various positions correct on that?

Mr. JASINOWSKI. Yes, sir, Mr. Chairman. The alliance felt that it ought to be targeted and focused and that we ought not to have it broadly but that it was essential to have it, that if you didn't have it you were doing all of this without any final requirement for action. I mean there must be action, it needs to be targeted.

The CHAIRMAN. Would it be worth while perhaps to target the judicial review at only the most extraordinary circumstances? In other words, take the very big kinds of sectors where you have \$200 million or \$500 million worth of costs to the economy coming out of a particular thing and say that we had judicial review in

those cases and an administrative procedures review in cases of lesser consequence, is that—

Mr. JASINOWSKI. I think that we want to work with the committee on the definition of the criteria but that it just makes common sense to suggest that you ought to deal with the largest first and there ought to be some notion of other ways in which there could be harm, and I don't know what those are altogether. They must have to do with some definition of health and safety and so forth. But I think that that is the right direction because it is the common sense approach.

The CHAIRMAN. And I gather that there is general agreement among this panel that while we will hear from the agencies about the tremendous new cost burdens that this will impose upon them, that would only be the case if, in fact, what they did was basically added this to the top of what they are doing now, that what this committee should be exploring is ways of trying to reshape those agencies so that what they are doing takes this into account as a part of their work and simply doesn't add it as one more layer of extra work upon the agency but rather restructures the agency so that this could be done within present budget.

Mr. GRAHAM. Yes, I think that is an excellent point, because imagine if they were to create a separate part of their bureaucracy and call it risk analysis and cost-benefit analysis, and if that were never integrated into the normal activities of how rule-makings are developed or how agency decisions are made, we would have a very difficult, I think, management problem in those agencies. So this has got to be built into the way they do their business.

The CHAIRMAN. And I think that is exactly where they intend to go based upon some of the preliminary information that we have seen, that that is kind of what—what they see this as doing is giving them one more place where they are now going to add a brand new function at tremendous new cost and then tell the committee about all these horrendous costs that their agencies are going to have to bear.

Mr. Jasinowski.

Mr. JASINOWSKI. Mr. Chairman, this reminds me of what went on in the private sector back in the early 1980's where people used to just keep adding things and adding things and it was just ridiculous, and then people began to realize they were going out of business because of that, and then they were forced to do a Total Quality Management program which developed a new culture which said you had to do everything different.

I mean there is a quote from Peter Drucker that says each day you have got to look at this anew and do it differently, and I think we are trying to change the culture to say that old way of doing it just didn't work any more and that if you want a real quality environmental program you have got to look at bringing risk and cost-benefit analysis into it and get rid of some things that you are now doing that don't make sense.

The CHAIRMAN. Mr. Kazman.

Mr. KAZMAN. I think you are going to be hit with the equivalent of what is known as the Washington Monument strategy. That is, you make a demand on the agency, they say, well, that that means

we will have to close down the Washington Monument, and they hope the ensuing public outcry causes you to change course.

One approach to take on this if you are really worried about growth in agency budgets is just to freeze their budgets, force them to do this, and allow them to put in terms of priority what is most important and what is least important. That way you would at least know that this job gets done for the most important things and that agency on net will not be growing.

The CHAIRMAN. In this case we will analyze whether closing the Washington Monument will prevent somebody from jumping from the top of it and thereby save lives.

Mr. KAZMAN. Well, you know, it does look like a toothpick, if you think about it.

[Laughter.]

Mr. BAKER. Mr. Chairman, would you yield?

The CHAIRMAN. The gentleman from California—briefly.

Mr. BAKER. As the pincer motion, the passage of the unfunded mandates bill which will sail out of here after another 200 amendments, so that we can't force our regulations down on local governments to pay for them, and the balanced budget amount which will also eventually find its way to the State, meaning we have to pay for everything in the future, not put it on our grandkids, will force us to be more efficient in the regulatory area. So those two things together are going to say to agencies, "If you want an additional rule, it has to make sense," and so you folks are going to be the ones there saying we will help you make that analysis.

So I think this is an extremely important piece of legislation at this particular time in the history of the Federal Government.

The CHAIRMAN. I thank the gentleman.

Are there any other members that have other questions before we dismiss the panel?

I thank the panel. I thank the members for their participation. The hearing stands adjourned.

[Whereupon, at 1:08 p.m., the committee was adjourned.]

## APPENDIX

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NATIONAL  
GOVERNORS'  
ASSOCIATION



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Statement Submitted for the Record  
E. Benjamin Nelson  
Governor of Nebraska

before the

Committee on Science  
United States House of Representatives

on

“Governors’ Perspectives on Risk Analysis and Priority-Setting”

on behalf of

The National Governors’ Association

January 31, 1995

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE, I'M BEN NELSON, GOVERNOR OF NEBRASKA. I AM REPRESENTING THE NATIONAL GOVERNORS' ASSOCIATION. WE APPRECIATE THE OPPORTUNITY TO PROVIDE INPUT ON THE RISK PROVISIONS IN H.R. 9 OF THE "CONTRACT WITH AMERICA" BEFORE THE COMMITTEE TAKES ACTION ON THE BILL.

FOR NEARLY TWO YEARS, I HAVE BEEN A LEADER AND ADVOCATE FOR DEVELOPING STRATEGIES TO PROVIDE RELIEF FROM UNFUNDED MANDATES PASSED DOWN FROM THE FEDERAL GOVERNMENT TO STATE AND LOCAL GOVERNMENTS. I BELIEVE THAT OUR EFFORTS TO REDUCE MANDATES WILL BE REINFORCED BY PROVISIONS FOR RISK ANALYSIS AND PRIORITY-SETTING AT THE STATE AND LOCAL LEVELS, PARTICULARLY IN ENVIRONMENTAL PROGRAMS. ALL TOO OFTEN, STATE AGENDAS ARE VICTIMIZED BY CRISIS-DRIVEN STATUTES AND ILL-FITTING FEDERAL SOLUTIONS. THE SCIENCE OF RISK ASSESSMENT MAY NEVER BE PERFECT, BUT THE TIME HAS COME TO FULLY INCORPORATE CONSIDERATION OF RISKS, PRIORITIES, PUBLIC HEALTH BENEFITS, AND COST-EFFECTIVENESS INTO FEDERAL DECISIONMAKING.

THE PROVISIONS CONTAINED IN TITLE III OF H.R.9 DEMONSTRATE A CLEAR CONGRESSIONAL COMMITMENT TO MOVE LEGISLATION THAT REQUIRES FEDERAL AGENCIES TO CONDUCT AND CONSIDER THE RESULTS OF RISK ASSESSMENTS AND COST-BENEFIT ANALYSES IN DEVELOPING FEDERAL REGULATIONS AND STANDARDS. THE BILL CONTAINS MANY ELEMENTS OF THE RISK POLICY LANGUAGE THAT THE SENATE OVERWHELMINGLY APPROVED AS AN AMENDMENT TO THE SAFE DRINKING WATER ACT LAST YEAR.

GOVERNORS STRONGLY SUPPORT RISK REDUCTION PRINCIPLES IN THE DEVELOPMENT OF ENVIRONMENTAL REGULATIONS AND COMMEND YOUR PURSUIT OF THIS LEGISLATION. HOWEVER, WE BELIEVE IT IS ESSENTIAL THAT SUCH ANALYSES FOCUS ON COST-EFFECTIVENESS BY REQUIRING AGENCIES TO IDENTIFY THE LEAST COSTLY REGULATORY ALTERNATIVES THAT ACHIEVE RISK REDUCTIONS. FOR MANY ENVIRONMENTAL STANDARDS, IT IS NOT FEASIBLE TO QUANTIFY THE PUBLIC HEALTH BENEFITS RELATIVE TO THE ECONOMIC COST OF IMPLEMENTING THE STANDARD. CONSEQUENTLY, ANY REQUIREMENTS FOR RISK ANALYSIS MUST CLEARLY ALLOW FOR THE INCORPORATION OF QUALITATIVE MEASURES OF PUBLIC HEALTH BENEFITS.

IN PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT, THE GOVERNORS ARE COMMITTED TO ACHIEVING RESULTS BASED ON THE PRINCIPLES EMBODIED IN THE NGA POLICY STATEMENT ON ENVIRONMENTAL PRIORITIES AND UNFUNDED MANDATES, WHICH I HAVE ATTACHED TO MY STATEMENT FOR THE RECORD. REQUIREMENTS ESTABLISHED UNDER EXISTING LAWS AND REGULATIONS ARE INCREASINGLY BURDENSOME, LESS THAN COST-EFFECTIVE, AND IMBALANCED IN TERMS OF ADDRESSING PRIORITY PROBLEMS FIRST. THE GOVERNORS BELIEVE THAT THE DAYS WHEN WE COULD AFFORD TO "DO IT ALL" HAVE LONG GONE, IF THEY EVER EXISTED. TODAY WE HAVE TO SET PRIORITIES, CHOOSE AMONG MANY COMPETING DEMANDS FOR OUR RESOURCES, AND SPEND THE PUBLIC'S MONEY--OR USE REGULATIONS TO MAKE THE PUBLIC SPEND ITS OWN MONEY--MORE CAREFULLY.

AS AN EXAMPLE, CONSIDER THE SAFE DRINKING WATER ACT. ALTHOUGH YOU MAY FIND IT HARD TO BELIEVE, THE CURRENT DRINKING WATER LAW IS "BLIND" TO THE AMOUNT OF RISK REDUCTION ACTUALLY OBTAINED BY A GIVEN DRINKING WATER STANDARD. THE CURRENT LAW REQUIRES THE ENVIRONMENTAL PROTECTION AGENCY (EPA) TO SET THE STANDARD AT THE MOST STRINGENT LEVEL ACHIEVABLE BY TECHNOLOGY, EVEN IF THAT TECHNOLOGY IS MANY TIMES MORE EXPENSIVE AND ONLY marginally more effective than available alternatives, AND WITHOUT CONSIDERATION OF PUBLIC HEALTH RISK REDUCTION BENEFITS. EPA TAKES COST INTO CONSIDERATION BY ANALYZING WHETHER *A LARGE SYSTEM CAN AFFORD THE BEST TECHNOLOGY*, BUT THE QUESTION OF HOW MUCH PUBLIC HEALTH BENEFIT IS ACTUALLY OBTAINED MAY NOT BE TAKEN INTO ACCOUNT.

FOR EXAMPLE, IN NEBRASKA THE POPULATION IN 70 PERCENT OF OUR COMMUNITIES IS LESS THAN 500 PEOPLE, THE POPULATION IN 80 PERCENT IS LESS THAN 1,000 PEOPLE, AND THE POPULATION IN 91 PERCENT IS LESS THAN 2,500 PEOPLE. UNDER ANY DEFINITION, THESE ARE NOT LARGE CITIES AND THEY DO NOT HAVE LARGE PUBLIC WATER SUPPLY SYSTEMS. AS A RESULT, THE ECONOMIES OF SCALE PRODUCE A SEVERE PENALTY FOR THE RESIDENTS OF THESE SMALLER COMMUNITIES. DRINKING WATER STANDARDS SHOULD BE SET BASED ON COSTS AND BENEFITS, NOT BASED ON TECHNOLOGIES THAT ARE AFFORDABLE ONLY TO THE LARGEST SYSTEMS.

MORE THAN ANYTHING ELSE, THE DEBATE ON RISK REDUCTION IS A DEBATE ON PRIORITIES AND WHO SETS THEM. WHEN THE CONGRESS DECREES THAT ALL DRINKING WATER SHOULD BE CLEANED UP TO THE HIGHEST ACHIEVABLE LEVEL, IT IS REALLY SAYING THAT BUYING THAT ULTIMATE DEGREE OF PROTECTION, REGARDLESS OF ITS COST OR THE DEGREE OF MEANINGFUL HEALTH BENEFIT IT WILL PROVIDE, IS MORE IMPORTANT THAN OTHER PURPOSES FOR WHICH OUR MONEY MIGHT BE SPENT--MORE IMPORTANT THAN OTHER PUBLIC INVESTMENTS, SUCH AS EDUCATION AND PUBLIC SAFETY.

AN ESSENTIAL COMPONENT TO YOUR REGULATORY REFORM AGENDA SHOULD BE ADOPTION OF A MECHANISM THAT ENABLES STATES TO UTILIZE COST-EFFECTIVE RISK REDUCTION ANALYSIS AS A TOOL IN DIRECTING RESOURCES TOWARD STATE AND LOCAL PRIORITY ENVIRONMENTAL PROBLEMS. SOUND SCIENCE AND RISK REDUCTION PRINCIPLES, INCLUDING THE APPROPRIATE USE OF COST-BENEFIT ANALYSIS THAT CONSIDERS BOTH QUANTITATIVE AND QUALITATIVE MEASURES, WILL PROVIDE GREATER ASSURANCE THAT STATES WILL GET A GOOD RETURN ON RESOURCES INVESTED IN A PARTICULAR ENVIRONMENTAL ACTIVITY. IN TURN, INVESTMENTS ON PRIORITY NEEDS WILL OPTIMIZE THE AMOUNT OF ENVIRONMENTAL PROTECTION "BOUGHT" WITH THE FINITE RESOURCES AVAILABLE BY PROMOTING ADOPTION OF REGULATORY ALTERNATIVES THAT EFFECTIVELY REDUCE RISKS AT THE LEAST COST.

PRIORITY-SETTING MECHANISMS MUST BE IMPLEMENTED TO PUT ENVIRONMENTAL PROBLEMS INTO PERSPECTIVE, RATHER THAN CONSIDERING EACH ONE IN ISOLATION AS IS NOW THE CASE. FOR EXAMPLE, IN CONSIDERING LEGISLATION ON CLEAN WATER, CONGRESS SHOULD RECOGNIZE THAT THE RISKS AND BENEFITS ASSOCIATED WITH THE PROBLEMS CONGRESS IS ADDRESSING MAY BE GREATER OR SMALLER THAN THE RISKS AND BENEFITS ASSOCIATED WITH DRINKING WATER, AIR QUALITY, OR OTHER ENVIRONMENTAL PROBLEMS THAT EPA AND STATES MUST ADDRESS UNDER EXISTING LAW. IN RECOGNIZING THESE RELATIONSHIPS, CONGRESS SHOULD PROVIDE EPA AND THE STATES WITH THE OPPORTUNITY TO EVALUATE SUCH RELATIONSHIPS AND TAKE RESPONSIBILITY FOR PRIORITIZING THE USE OF AVAILABLE RESOURCES IN ORDER TO PROMOTE THE GREATEST PUBLIC GOOD.

AS AN EXAMPLE, IN NEBRASKA I HAVE DIRECTED AN INTERAGENCY TEAM TO DEVELOP A PROCESS BY WHICH STATE AND LOCAL OFFICIALS WILL SIT DOWN TOGETHER AND REVIEW ENVIRONMENTAL MANDATES THAT ARE IMPOSED BY FEDERAL AND STATE LAWS. WE WILL JOINTLY EVALUATE THE REALISTIC RISKS COMMUNITIES FACE AS WELL AS THEIR FISCAL AND HUMAN RESOURCE CAPACITY TO ADDRESS THOSE RISKS IN A COST-EFFECTIVE MANNER. FROM THIS PROCESS, STATE AND LOCAL OFFICIALS WILL DEVELOP A SCHEDULE FOR THE COMMUNITY TO COMMIT RESOURCES TO MEETING THOSE REQUIREMENTS THAT ADDRESS THE GREATEST RISKS FIRST. OUR OBJECTIVE IS TO FOSTER RESPONSIBLE EFFORTS TO ACHIEVE ENVIRONMENTAL COMPLIANCE BASED ON REALISTIC EXPECTATIONS.

I BELIEVE THAT PRIORITY-SETTING IS ALSO FUNDAMENTAL TO REFORMING THE "ONE-SIZE-FITS-ALL" APPROACH TO FEDERAL REGULATIONS. AS DEMONSTRATED BY OUR EXPERIENCE IN NEBRASKA, AND IN ALMOST ALL STATES, FLEXIBILITY IN MEETING NATIONAL GOALS AND STANDARDS LEADS TO MORE SUCCESSFUL OUTCOMES. ASSESSING ENVIRONMENTAL AND HEALTH RISKS, IN CONJUNCTION WITH COST-EFFECTIVE REGULATIONS, WILL EMPOWER STATES AND CITIES TO IMPLEMENT RESPONSIBLE SOLUTIONS THAT MAKE SENSE FOR CITIZENS, NOT GOVERNMENT BUREAUCRATS.

LET ME GIVE YOU AN EXAMPLE OF A SUCCESSFUL STATE SOLUTION IN THE CONTEXT OF THE 1990 CLEAN AIR ACT AMENDMENTS, A FEDERAL STATUTE WITH MANY RIGID REQUIREMENTS THAT HAS RESULTED IN PRESCRIPTIVE REGULATIONS. BACK IN THE 1980S, BEFORE AIR QUALITY IMPROVEMENTS WERE DICTATED SO PRESCRIPTIVELY BY FEDERAL STATUTE AND REGULATIONS, THE LAW REQUIRED STATES TO ATTAIN THE FEDERAL STANDARDS WITHOUT TELLING US WHICH MEASURES TO IMPLEMENT. UNDER THIS SCENARIO, NEBRASKA IMPLEMENTED A STATE-DEVELOPED STRATEGY WITH OXYGENATED FUELS AND OTHER TRANSPORTATION MEASURES AND EFFECTIVELY IMPROVED AIR QUALITY IN THE CITIES OF LINCOLN AND OMAHA TO MEET FEDERAL STANDARDS.

A COMPREHENSIVE PERSPECTIVE BASED UPON THE BEST OBTAINABLE SCIENTIFIC, TECHNICAL, ECONOMIC, AND OTHER INFORMATION WILL BETTER ENABLE FEDERAL AND STATE POLICYMAKERS TO DETERMINE HOW MUCH, IF ANY, NEW REGULATION IS

APPROPRIATE FOR ENVIRONMENTAL PROGRAMS. THE GOVERNORS ARE COMMITTED TO ENGAGING IN A DIALOGUE TO IDENTIFY WAYS OF REINVENTING ENVIRONMENTAL PROTECTION IN A MANNER THAT SUPPORTS PRIORITIZATION OF PROBLEMS FOR ALL ENVIRONMENTAL MEDIA.

IN SUPPORT OF THESE OBJECTIVES, WE WOULD LIKE TO WORK WITH YOU TO DEVELOP A PRIORITY-SETTING FRAMEWORK THAT ENABLES STATES TO DIRECT RESOURCES TOWARD STATE AND LOCAL PRIORITIES, POSSIBLY THROUGH AN ENVIRONMENTAL BLOCK GRANT. STATE PRIORITIES, DEVELOPED IN CONSULTATION WITH LOCAL OFFICIALS AND BASED UPON THE BEST AVAILABLE SCIENTIFIC INFORMATION ON ENVIRONMENTAL AND HEALTH RISKS, SHOULD BE USED TO ALLOCATE RESOURCES TO THE MOST PRESSING STATE ENVIRONMENTAL PROBLEMS. THE GOVERNORS GENERALLY SUPPORT CONSIDERATION OF SUCH PROPOSALS TO PROVIDE SUBSTANTIAL STATE FLEXIBILITY WITH ADMINISTRATIVE SAVINGS. HOWEVER, BLOCK GRANT PROPOSALS SHOULD NOT BE USED TO SHIFT THE COSTS OF FEDERAL PROGRAMS TO STATE AND LOCAL GOVERNMENTS. BLOCK GRANT PROPOSALS SHOULD BE DESIGNED TO ENCOURAGE AND REWARD STATE AND LOCAL EFFORTS TO DEVELOP MORE INNOVATIVE AND COST-EFFECTIVE PROGRAMS.

FINALLY, I WOULD LIKE TO RAISE A RELATED REGULATORY REFORM ISSUE THAT IS VERY IMPORTANT TO STATE AND LOCAL ELECTED OFFICIALS. AS COREGULATORS OF MANY FEDERAL PROGRAMS, STATE AND LOCAL OFFICIALS SHOULD BE EXEMPT FROM THE FEDERAL ADVISORY COMMITTEE ACT (FACA). THE IMPORTANCE OF AN EXEMPTION DOES NOT LIE IN THE SPECIFICS OF FACA AND HOW IT GOVERNS ADVISORY COMMITTEES, BUT IN THE FACT THAT FACA IS CURRENTLY USED BY THE FEDERAL GOVERNMENT TO SERIOUSLY HAMPER, AND IN SOME CASES PROHIBIT, MEANINGFUL CONSULTATION AMONG FEDERAL, STATE, AND LOCAL ELECTED OFFICIALS WHO ARE CHARGED WITH IMPLEMENTING THE SAME ENVIRONMENTAL REQUIREMENTS.

FACA WAS NEVER INTENDED TO APPLY TO STATE AND LOCAL GOVERNMENT OFFICIALS, AND AN EXEMPTION IS AN ESSENTIAL COMPONENT OF THE BROADER EFFORT TO RESTORE BALANCE TO THE STATE-FEDERAL RELATIONSHIP. WITHOUT AN EXEMPTION, GOVERNORS, LEGISLATORS, COUNTY SUPERVISORS, AND MAYORS ARE NOT RECOGNIZED FOR THEIR UNIQUE RESPONSIBILITIES IN IMPLEMENTING FEDERAL

PROGRAMS. LET ME CLEARLY STATE THAT AN EXEMPTION FROM FACA DOES NOT IN ANY WAY IMPACT EXISTING OPPORTUNITIES FOR PUBLIC INPUT THROUGH THE ADMINISTRATIVE PROCEDURES ACT, WHICH PROVIDES EQUAL ACCESS FOR COMMENT BY ALL PARTIES, REGARDLESS OF STATUS. EARLY CONSULTATION WITH STATE AND LOCAL OFFICIALS, FOLLOWED BY PUBLIC INPUT, RESULTS IN MORE EFFECTIVE FEDERAL PROGRAMS.

THE GOVERNORS REMAIN COMMITTED TO THE PASSAGE OF LEGISLATION THAT WILL RESULT IN MORE EFFECTIVE ENVIRONMENTAL PROTECTION AND PROVIDE NEW OPPORTUNITIES TO SATISFY FEDERAL REQUIREMENTS BASED ON STATE AND LOCAL PRIORITIES. WE LOOK FORWARD TO CONTINUING TO WORK TOGETHER ON THESE IMPORTANT ISSUES.

THAT CONCLUDES MY WRITTEN STATEMENT. MR. CHAIRMAN AND MEMBERS, THANK YOU FOR THE OPPORTUNITY TO PROVIDE GOVERNORS' PERSPECTIVES ON THIS ISSUE.

**WRITTEN TESTIMONY ON  
RISK ASSESSMENT FOR ENVIRONMENTAL RULE MAKING**

K. Jack Yost<sup>1</sup>

I am pleased to offer this testimony pertaining to the use of risk assessment in the development and enforcement of U.S. laws, regulations, and rules pertaining to environmental issues. Penn State has considerable expertise in this area, and I have personally been active in the field for more than 15 years.

In preface to my remarks, let me state that I was encouraged to learn of Chairman Walker's plan to explore and promote risk assessment as a basis for developing environmental regulations. We believe that this initiative can do much to bolster U.S. economic competitiveness without adversely impacting the environment. Simply put, incorporating risk assessment methodologies in the environmental rule making process provides the foundation for "sustainable economic development."

Risk assessment is intrinsic to human life. We constantly, consciously and unconsciously, make risk assessments on which we base choices. These decisions

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<sup>1</sup> Dr. K. Jack Yost is currently the Associate Vice President for Research and Technology Transfer at The Pennsylvania State University. In that capacity, he administers a University research budget in excess of \$300 million dollars. He also chairs the University's Administrative Committee on Research and the Environmental Science and Technology Council. Formerly, at Purdue University, Dr. Yost directed a number of multi-million dollar environmental research projects. The primary product of these projects is a comprehensive risk assessment software system designed for developing risk-based environmental regulations. The Federal Health Office (*Bundesgesundheitsamt*) of the Federal Republic of Germany has based their dietary risk assessment protocol on these methods.

## RISK ASSESSMENT FOR ENVIRONMENTAL RULE MAKING

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must often be made with incomplete or even flawed data. Over the past 20 years, universities, industry, and the military have developed improved algorithms for reducing uncertainty and improving decision making under uncertain conditions. I would like to describe a model for environmental rule making that incorporates these advances.

The model I'll relate pertains to "trace" substances in the environment; these are substances that are present in minute quantities. The model includes six phases:

- Substance Identification
- Identification of Exposed Populations
- Toxicity Assessment
- Determination of Maximum Acceptable Exposure
- Cost-Benefit Analysis
- Rule making

The *substance identification* phase focuses on building the foundation for all subsequent efforts. Specific tasks include: identification of potentially hazardous trace substances as well as their associated sources and fates (rates, routes, and concentrations); and stakeholder identification. Substance fate is among the areas which can be most readily quantified. Further, ecosystem modeling, both computer- and heuristically-based, is now capable of addressing

## RISK ASSESSMENT FOR ENVIRONMENTAL RULE MAKING

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cross-compartment migration both in terms of the rates of substance migration and routes by which migration takes place. The term “cross-compartment” refers a change in media (air, water, or land) or geographic area. Existing rules and regulations are generally based upon a simplified, compartment-by-compartment, view of the environment.

The second phase, *identification of the exposed populations*, is derived directly from the first. When the fate of a potentially hazardous substance is determined (where it is and in what concentrations), we will know both the exposed populations and their level(s) of exposure.

*Toxicity assessment* is the phase that contains the greatest uncertainty. Toxicity usually is expressed in terms of a range of concentrations within which the threshold of detrimental impact (morbidity, mortality, etc.) for human or biotic populations lies. Toxicity estimates are likely to be based upon epidemiological studies, animal studies, or comparisons to other similar substances. These methods either lack scientific controls or require extrapolations that reduce certainty, requiring the use of extremely wide toxicity ranges.

The fourth through sixth phases, *determination of maximum acceptable exposure*, *cost-benefit analysis*, and *rule making*, are potentially the most contentious. This makes early stakeholder involvement in the risk assessment and rule making process extremely important. The *determination of maximum*

## RISK ASSESSMENT FOR ENVIRONMENTAL RULE MAKING

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*acceptable exposure* is based on toxicity estimates. Presently, the maximum acceptable exposure associated with most (non-carcinogenic) toxic substances generally corresponds to a level 100 times less than the "no observed adverse effect level" determined through animal studies. Given the uncertainties associated with the determination of toxicity, this safety margin may be unnecessarily conservative.

I also advocate that *cost-benefit analyses* should be employed to rationally control exposure levels. This process enables one to relate specific exposure reductions, and estimated impacts, to the cost of proposed or extant environmental regulations. In this phase, stakeholder participation is particularly crucial. Previous efforts at cost benefit analyses have sometimes been criticized for overestimating the benefits and underestimating costs. Active and open participation by all stakeholders can reduce perceptions of bias in cost-benefit analyses.

The first five phases provide a factual and informed basis for the final *rule making* process. The result is a more balanced presentation of both the qualitative and quantitative factors that should influence the rule making process.

In conclusion, analytical tools and methodologies have been developed over the past two decades that enable a more balanced approach to environmental rule making. The approach just described seeks to integrate state-of-the-art science

## RISK ASSESSMENT FOR ENVIRONMENTAL RULE MAKING

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with openly developed cost-benefit analysis. While this sort of methodology is far from perfect, it provides a basis for integrating the quantifiable and subjective elements of the rule making process.

**Written Comments of the  
Building Owners and Managers Association (BOMA)  
International**

**To the  
Committee on Science  
U.S. House of Representatives  
on  
Risk Assessment and Cost/Benefit Analysis**

**February 8, 1995**



**Building Owners and Managers Association International  
1201 New York Avenue, NW, Suite 300, Washington, DC 20005  
Phone: 202-408-2684 FAX: 202-371-0181**

The Building Owners and Managers Association (BOMA) International thanks you for the opportunity to submit written comments.

Founded in 1907, BOMA International is a dynamic federation of 98 local associations whose members own or manage over 6 billion square feet of commercial properties and facilities in North America. The membership -- composed of building owners, managers, developers, leasing professionals, facility managers, asset managers, and the providers of goods and services -- collectively represents all facets of the commercial real estate industry.

Over the past years, the quantity of rules and regulations that face the public and private sectors have skyrocketed, but the funds to enact and comply with these regulations are becoming ever more scarce. While the majority of regulations are needed and effective to protect human health and the environment, all too often we see regulations enacted before sound scientific research is undertaken -- in response to public hysteria, misinformation, perceived risks, media pressure, or misguided mandates.

In the 1980's, public hysteria and premature actions by the Environmental Protection Agency led to the expense of billions of dollars. Schools were mandated, and building owners strongly pressured, to remove all asbestos, friable or non-friable, before the facts were in. By the time EPA discovered that one fiber does not kill, that the most common form of asbestos does not pose a significant health risk, and that asbestos in good condition is best managed in-place, billions of dollars had already been spent abating asbestos.

Despite the lessons learned from the asbestos debacle, the regulation-before-science approach still occurs. Presently, the Occupational Safety and Health Administration (OSHA) is in the rulemaking process, having issued an \$8.1 billion proposed rule on indoor air quality. BOMA, and many other industry experts and scientists, believe that much of OSHA's data and assumptions are seriously flawed. OSHA has proceeded to issue this proposal before determining:

- the true scope of indoor air problems;
- the cause of the problems;
- the proven effective ways to prevent or mitigate the problems; and
- the cost/benefit ratio to assess whether or not the impact of the rule is feasible and sound.

Indoor air quality problems do not constitute an epidemic sweeping the nation. The situation comes nowhere near the level cited by OSHA. Office building owners and

managers have more than adequate incentive to provide high quality indoor air. What is needed is good research on what causes problems to develop so that immediate and effective steps can be taken to prevent or remove problems altogether. An \$8.1 billion regulation based on flawed reports, anecdotal evidence and burgeoning hysteria is poor public policy and should be addressed responsibly through implementation of a sound risk assessment program.

Had EPA conducted more thorough research prior to making faulty assumptions on the risk of asbestos, billions of dollars that were wasted could have been targeted towards other programs or higher priority risks. Had OSHA undertaken a formal peer review as would be required under H.R. 9, we believe that OSHA would have discovered that poor indoor air is not an epidemic and does not merit its annual compliance cost of \$8 billion - funds that the public sector will take away from other programs and costs that the private sector will be forced to charge the consumer.

Clearly, risk assessment, cost-benefit analysis, and peer review are tools that must be incorporated into the regulatory process.

Thank you again for the opportunity to provide written comments. If you or your staff have any questions or require additional information, please contact Jim Dinegar or Karen Penafiel at (202) 408-2684.

**Building Owners and Managers Association International**  
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American Dental Association

**STATEMENT**

**SUBMITTED TO THE**

**COMMITTEE ON SCIENCE**

**U.S. HOUSE OF REPRESENTATIVES**

**ON THE**

**JOB CREATION AND WAGE ENHANCEMENT ACT**

**(H.R. 9)**

**FEBRUARY 15, 1995**

Washington Office: 1111 14th Street NW Washington DC 20005 (202) 898-2400

Background

The American Dental Association is encouraged by the introduction and consideration of legislation (H.R. 9) which in part would revise the federal regulatory process. These initiatives are, in our opinion, long overdue. The comments which follow are intended to emphasize the particular need for regulatory relief in the health care sector - an issue which we respectfully submit has not been adequately addressed by the Congress during its hearings and deliberations on the legislation. Reform of government rule-making is not and should not be an objective prompted solely by concerns related to business and industry. The consumer is equally affected by ill-advised regulations that are imposed upon the delivery of health care services.

Over the past five years the practice of dentistry has been subjected to a series of excessive, intrusive and costly federal rules. These regulations, however well intended, share a common critical flaw: the failure to recognize that questions of worker safety, hazard abatement and environmental protection have, when applied to the dental setting, a direct impact upon larger social issues of access to and quality of oral health care. It is not simply a matter of added product costs to the consumer for an appliance, automobile, etc.

To cite one example, the Occupational Safety and Health Administration promulgated a standard on infection control in 1991. The agency projected that the annual expense of compliance would be \$87.4 million. A recent comprehensive survey and analysis of dental infection control and OSHA compliance costs found the actual yearly cost to meet the standard exceeds \$2.7 billion. This represents an average annual per-dental practice expense of \$23,713. For consumers, this translates into an unavoidable increase in their dental care costs. The Health Care Financing Administration (HCFA) has just cited a new and "atypical trend" in dental spending: up \$7 billion in three years. HCFA actuaries attribute this rise in oral health prices to the cost of infection control practices and procedures.

Unlike medicine, 53% of the expense of oral health care is paid for out-of-pocket rather than by insurance or government programs. The dental market is largely driven by economics. Faced with higher costs, patients may defer needed treatment. The nation's public health will suffer the consequences. Finally, it must be noted, there has never been a single documented instance of a dental worker acquiring HIV from occupational exposure; either before the 1991 OSHA standard was invoked or since. Hepatitis B is another bloodborne disease of concern to dentists and their office staff. However, the last outbreak of Hepatitis B transmission in a dental practice was

reported in 1986, well before the OSHA standard took effect. This can be attributed to widespread immunization and the routine use of barrier techniques voluntarily undertaken by the profession in the 1980's. Additional examples of irrational federal regulatory actions are attached to this statement.

The Association is not reflexively opposed to regulation. Dentistry has a history of public health advocacy dating back more than a century. The dental profession has voluntarily established and complied with a range of standards to ensure a safe clinical environment for members of the dental team and the patients they serve. When federal guidelines are deemed necessary, they should be relevant if applied to the practice of dentistry and, most importantly, the benefits to society should clearly outweigh the costs imposed on society. This has not been the experience of the American Dental Association.

#### Risk Assessment and Cost-Benefit Analysis

Title III of H.R. 9 represents a positive beginning in addressing the need for proper risk assessment and cost-benefit analysis. The Association has, however, two concerns.

It is imperative that any final legislation require federal regulatory bodies to examine presumed occupational and environmental risks on an industry-specific basis. One size does

not fit all. Dental care is provided in a well-controlled and predictable environment. That setting and its potential for risk to injury or exposure is substantially different from the automobile industry, a chemical plant or the emergency room of a hospital. Nonetheless, two OSHA regulations - the Hazard Communication Rule and the aforementioned Bloodborne Pathogen Standard - were applied to dentistry with little if any assessment of the relative risks among categories of workers covered.

Secondly, and of equal importance, a look-back authority should be adopted; one that establishes a mechanism to systematically address existing regulations that have proven to be difficult to comply with as well as needlessly expensive, while yielding little discernable benefit to the regulated class or the general public. In dentistry, this would certainly include the OSHA Hazard Communication Rule and portions of the Bloodborne Pathogen Standard.

On the broader issues of risk assessment and risk management, there is a growing body of informed opinion that (1) scientific analysis must be disentangled from policy judgments, (2) that an overly conservative approach is not helpful in reaching accurate approximations of true risks and (3) that the risk assessment process needs to be made open to the regulated community and the public.

This Association agrees with the critics of what is known as "plausible conservatism". To present the end result of a complex, multi-step risk assessment only in terms of an upper-bound estimate (i.e., a worst-case scenario) is to invite the selection of trivial risks for regulatory action. In other words, the overstatement of risks carries its own risks.

Beyond this, an overly conservative approach undermines agency credibility, feeds public disbelief and ridicule and wastes limited resources.

The Association therefore welcomes Title III requirements that risks be more fully characterized to include lower-bound and mid-range estimates, as well as acknowledgment of uncertainties.

The Association supports the concept that risk assessments and cost-benefit analyses should be subjected to outside peer review. This will enhance public trust and help prevent what agencies say they fear, which is the "freezing" of science. Instead, outside scientific review will ensure that in-house science remains current.

Elaborate peer review mechanisms need not be established for every rulemaking, but they should be required for every major rulemaking, especially where scientific uncertainties must be weighed against substantial societal costs. For example, the

anticipated OSHA ergonomics proposal and the pending Indoor Air Quality Rule are good examples of agency initiatives that should be subjected to an independent scientific review.

Titles IV-VIII of the legislation compliment the regulatory reform initiatives noted above. Specifically, the Association endorses those provisions of H.R. 9 which would

- \* in Title IV, establish procedures to limit the aggregate cost to the private sector of complying with federal rules;
- \* in Title V, require the government to reduce the paperwork burden imposed by federal regulations;
- \* in Title VI, determine the economic impact of rules on small businesses;
- \* in Title VII, mandate specific review criteria on the cost-effectiveness of government regulations affecting 100 or more individuals;
- \* in Title VIII, provide a "Citizens Bill of Rights" during regulatory inspections and enforcement.

#### Negotiated Rulemaking

Executive Order #2866, publicly announced by the President on September 30, 1993, outlined a broad effort to streamline the federal rulemaking apparatus and to make it more inclusive and responsive to affected parties. This concept which is consistent with the reforms proposed in H.R. 9, should be incorporated within the legislation.

The order requires each agency to identify "at least one" target

for negotiated rulemaking. The agency of most interest to dentistry, OSHA, responded minimally by choosing just one target. It is a rulemaking pertaining to the construction industry and because it is not yet complete, the results of this limited test are not yet clear. We are concerned that if good faith is not demonstrated by all parties involved in this test, then a very attractive concept may prematurely be jettisoned.

Executive Order #2866 and related memoranda contained other useful ideas which should be considered by the Congress. To improve participation by small businesses, for example, the Administration sponsored a Small Business Forum on Regulatory Reform in March 1994.

Executive Order #2866 also emphasized openness in the regulatory process, and instructed agencies to provide for "meaningful participation" earlier in the process. But, as the Office of Information and Regulatory Affairs acknowledged in its own report card (May 1994)," it is difficult to know how much advance consultation is actually taking place". This presents, in our opinion, a basis for Congressional action.

#### Enforcement

The American Dental Association believes that voluntary compliance is, for the health community, the most effective

approach to prevent occupational injury or illness.

Consultation, education, incentives and warning notices will ultimately produce greater results than regulations which emphasize punishment and intimidation as enforcement tools. The dental office is a unique workplace. It is a setting in which highly educated and trained health personnel provide patient care. Dentists work side-by-side with their staff. Any risk is by definition a shared risk. Thus, a very personal incentive is present to protect against hazards, illness or injury. Dentists, both as health professionals and as small employers, are overwhelmingly willing to voluntarily comply with standards that are based on science and need, clearly stated and equitably applied. Accordingly, the Association urges the inclusion of provisions within H.R. 9 that would, for the health care sector, redirect the thrust of regulatory compliance to one which allows individual professional judgment and flexibility in meeting national guidelines.

Additional Reform

Because the consideration of H.R. 9 and related measures provide a singular opportunity to overhaul and improve government rulemaking, the Association urges Congress to also address the following, additional recommended reforms:

- \* Federal regulatory agencies should be **required** to provide affected parties with opportunities to participate meaningfully in the standard-setting process.
- \* Exemptions for small businesses should be expanded and random inspections should be eliminated.
- \* In cases of non-compliance, first-time offenders should merely be warned, not cited and fined.
- \* Enforcement inspections should be conducted only by trained personnel who are familiar with the industry, business, profession or trade under surveillance.

Conclusion

As this statement has attempted to demonstrate, matters of workplace safety are for dentistry inextricably linked to the delivery of oral health services. The professional judgment of a dentist with regard to occupational risk and patient care must not be compromised by federal rules. Regulatory reform, to be effective, should acknowledge this fundamental precept.

**ATTACHMENTS****DENTIST CITED FOR EXPOSURE TO NITROUS OXIDE**

Nitrous oxide is an anesthetic gas that is used in many dental offices. OSHA has no specific standard dealing with nitrous oxide, and the agency has never established a permissible exposure level (PEL) for its use. Nonetheless, OSHA appears to be moving toward enforcement of the recommended exposure level (REL) suggested by the National Institute for Occupational Safety and Health (NIOSH), even though the NIOSH REL is inconsistent with recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH) and cannot be achieved in the dental office with currently available technology.

In January 1995, OSHA cited a general dentist for failure to maintain employee exposure to nitrous oxide below 25 parts per million (PPM) over an 8-hour time-weighted average (TWA). OSHA proposed a penalty of \$750 for the alleged violation. OSHA cited as authority for the violation the general duty clause (Section 5(a) of the OSH Act) which requires employers to furnish a workplace free from recognized hazards.

Exposure to nitrous oxide at 25 PPM is not a recognized hazard. In 1994, NIOSH issued an "Alert" requesting assistance in controlling exposure to workers to nitrous oxide during the administration of anesthetic gas in medical, dental and

veterinary operatories. The Alert suggests a REL of 25 PPM, but notes that the ACGIH recommended exposure level is twice that amount, or 50 PPM.

With the citation, OSHA provided the dentist with a list of "feasible and effective" abatement methods. Some--such as using air supplied respirators--are not practical in dental offices because they would interfere with patient care. Others--like using a scavenger system and improved ventilation--are feasible, but they are not effective in maintaining exposure below 25 PPM. In a 1977 publication, NIOSH presented methods for limiting the concentration of waste nitrous oxide to 50 PPM based on the technical feasibility of then-existing controls. No changes in technology have occurred since 1977 to significantly effect the dentist's ability to reduce exposure below this level.

The dentist in this case has two unattractive choices. He can either settle with OSHA and agree to abate the alleged violation, or he can bring a legal challenge. The first option is risky. If the dentist fails to maintain exposure levels below 25 PPM, he runs the risk of being inspected again and cited for failure to abate. This offense carries penalties of up to \$7,000 per day for each day the violation continues. The second option is costly. The dentist would be required to hire an attorney at an estimated cost of \$5,000 to \$15,000, well above the amount of the proposed penalty, to bring a legal challenge.

## MIGRANT HEALTH CLINIC CITED OVER LAUNDRY

In September 1992, OSHA cited the Hidalgo County Health Care Corp. and proposed a penalty of \$1,750 because a dental clinic operated by the Corporation allowed its employees to take their gowns home to launder. In addition to the laundry citation, OSHA penalized the Corporation \$1,750 for allegedly failing to provide employees with information and training about formaldehyde and \$700 for allegedly failing to record an injury on the Form 200 log. The Corporation is a non-profit organization that for more than 20 years has provided medical and dental care to migrant workers and indigent residents along the U.S./Mexican border.

The laundry citation was issued despite the fact that the section of the bloodborne pathogens standard that requires employers to clean their employees' gowns was not in effect when the inspection took place in May 1992. The clinic had plans to implement the laundry provision by July 1, the deadline established by OSHA in the standard. Nonetheless, the inspector threatened to post an "imminent danger" sign where it could be seen by patients and employees if the clinic did not immediately comply.

The director of the dental clinic, a Public Health Service officer and specialist in infection control who developed an AIDS protocol for the U.S. Navy, was extremely concerned about the

effect posting an official warning sign would have on the clinic's clientele. He came to the American Dental Association for help with what he regarded as an unreasonable OSHA enforcement action. The Association agreed and paid the legal fees for the clinic to challenge OSHA. The case was settled when the agency withdrew all of the items classified "serious," including the laundry citation, and dropped all penalties, except \$350 for failure to make an entry on Form 200.

## RISK ASSESSMENT AND COST BENEFIT ANALYSIS

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FRIDAY FEBRUARY 3, 1995

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON SCIENCE,  
*Washington, D.C.*

The committee met, pursuant to call, at 11:33 a.m. in Room 2318, Rayburn House Office Building, Hon. Robert S. Walker [chairman of the committee] presiding.

The CHAIRMAN. The committee will come to order.

Today we will have our second day of hearings on Title III of H.R. 9, the risk assessment and cost-benefit analysis section of the Job Creation and Wage Enhancement Act. We will hear from Members of Congress, the administration, and public policy organizations and individuals regarding their views on the legislation before us.

[The prepared statement of Mr. Walker follows:]

Today, we will have our second day of hearings on Title III of H.R. 9, the Risk Assessment and Cost Benefit Analysis section of the Job Creation and Wage Enhancement Act.

We will hear from Members of Congress, the Administration and Public Policy Organizations and individuals regarding their views on the legislation before us.

Mr. BROWN. Mr. Chairman, you're setting too good an example on opening statements here. It's going to be very difficult to keep up with you.

I too am looking forward to this additional day of hearing, and the views of the witnesses that we will be hearing, both our distinguished colleagues and those from the administration. I, as I've indicated before, support the principles behind this bill and I think it will enjoy widespread support.

However, I am deeply concerned that in passing whatever legislation comes out of this committee, we do it with caution and foresight, and that we try and avoid making the process of risk assessment more onerous and difficult for the regulated community than it is at the present time. You may say that is going to be very difficult to do, but I can assure you that some of the language in the legislation has that potential.

And, Mr. Chairman, we are concerned about moving this bill too quickly and, at the appropriate time, I'm going to ask you to discuss with me the possibility of giving us a little more time. But I will do that later on.

The CHAIRMAN. Okay. Thank you, Mr. Brown.

(221)

Our first two witnesses today are Members of the House who have been actively involved in this issue. And I would recognize first the gentleman from New Jersey, the Honorable Dick Zimmer.

**STATEMENT OF THE HON. DICK ZIMMER, A REPRESENTATIVE  
IN CONGRESS FROM THE STATE OF NEW JERSEY**

Mr. ZIMMER. Thank you, Mr. Chairman. It's great to be back in the committee room, albeit at the other side of the table. I want to thank you for the opportunity to testify on Title III of the Job Creation and Wage Enhancement Act of 1995.

I congratulate you, Mr. Chairman, and your predecessor, Mr. Brown, for continuing efforts to bring risk assessment issues to the forefront of congressional debate. It's been nearly 12 years since my good friend and now former colleague, Don Ritter, first brought this issue before this committee. Though I was not in Congress at the start of this process, I'm glad to be here to finally witness sanity and good science being made a part of the Federal regulatory process.

Mr. Chairman, Title III of H.R. 9 takes a significant step forward in addressing many of the shortcomings of current environmental regulation. Title III requires a more open process, it requires greater use of peer review, and it requires cost-benefit analysis for major regulations.

I believe that Title III of H.R. 9 is a very good starting point to deal with these issues. However, we need to go further in setting a new environmental policy agenda for the next century, and that's why I introduced H.R. 690, the Risk Assessment and Cost Benefit Analysis Act of 1995. H.R. 690 includes a number of provisions to supplement and complement Title III. In the backbone of H.R. 690 is prioritization.

Let's tackle the worst problems first. Environmental regulations are costing the American taxpayer over \$130 billion annually, and I don't know if that's too much or too little, but I do know that we need to make sure that the money is spent wisely. Like any idealist, I'd like to address every environmental and health problem we have and get rid of every part per quadrillion of every potential contaminant, but we know that can't be done.

In the real world of limited resources, we have no choice but to establish priorities based on sound data and common sense. In short, worst first. H.R. 690 requires Federal agencies to focus their monetary and regulatory clout on the issues of—on the risks that pose the greatest dangers to human health and the environment. Tackling the worst first will ensure that we get the biggest bang for the buck and will help to eliminate obtrusive and unwarranted regulations that tinker at the margins of environmental problems.

I'm pleased to say that the language in 690 and the concept of prioritization has received the support from the Chemical Manufacturers Association and the Alloy Alliance for Reasonable Regulation, chaired by Jerry Jaznowski, the President of the National Association of Manufacturers. I believe copies of their letters are in your packet.

The Contract With America calls for a smaller, smarter Federal Government. H.R. 690 responds to that challenge by requiring gov-

ernment to be more efficient and accountable in protecting citizens from environmental and health risks.

H.R. 690 requires the Office of Science and Technology Policy to oversee interagency coordination of risk assessment procedures in order to optimize the use of limited resources, stop unnecessary government duplication, and enhance interagency communication and practices. It also requires OSTP to establish mechanisms for greater communication on risk assessment issues between Federal and State regulatory agencies, and periodically to assess the effectiveness of the new way of doing business in a report to Congress.

This will help us achieve the goal of the Contract for government to work smarter, quicker and cheaper. The science supporting risk assessment is not static. Federal agencies must acknowledge in a timely manner the need to consider the impact of new information and scientific understanding on previously conducted risk assessments.

To ensure that relevant new information is fully considered, H.R. 690 requires each affected agency to set up a formal process, including peer review and public comment, for consideration of new information on previously issued risk assessments. H.R. 690 requires OSTP to prepare an annual State of the Environment report. It's time we take a hard look at how effectively we're managing our environmental resources. We need to institute a process that will allow us to ensure that our objectives are targeted and achieved.

I view that, the report, as an environmental audit. Under my proposal, OSTP annually would review regulatory actions taken by the government and would tell us if we're reducing risk effectively and efficiently. I believe that the annual report is the kind of information Congress needs if it's to make wise changes in setting environmental policy goals.

As I stated earlier, I've crafted my legislation to meet the goals of the Contract With America. In a few instances, my bill takes a different approach to meeting those goals. In light of the testimony heard this week in both this committee and the Commerce Committee, I would urge Members to look at the way my bill deals with peer review and judicial review before the markup on these vital sections begin.

Making the risk assessment process more open and accountable is the first step in reforming existing environmental laws. However, it's not a silver bullet that many people would like it to be. A good portion of the blame for ineffective and wasteful regulations must fall on us, the United States Congress. We have too often responded to environmental problems by legislating fixes that are not based on sound scientific principles of risk.

It's vital that as Congress begins to reauthorize the major environmental statutes, it does not overlook the hard work done by this committee to bring good science into the process.

Thank you very much.

[The prepared statement of Mr. Zimmer follows:]

COMMITTEE ON WAYS AND MEANS  
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OVERSIGHT



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## CONGRESSMAN DICK ZIMMER

226 Cannon House Office Building • Washington, D.C. 20515 • (202) 225-5801

### STATEMENT OF CONGRESSMAN DICK ZIMMER HOUSE SCIENCE COMMITTEE HEARINGS ON TITLE III OF THE JOBS CREATION AND WAGE ENHANCEMENT ACT February 3, 1995 (as prepared for delivery)

Mr. Chairman, thank you for the opportunity to testify on title III of the Job Creation and Wage Enhancement Act of 1995. I congratulate you, Mr. Chairman, for your continuing efforts to bring risk assessment issues to the forefront of congressional debate. It has been nearly 12 years since my good friend and former colleague, Don Ritter, first brought this issue before this committee. Though I was not in Congress at the start of this process I am glad to be here to finally witness sanity and good science being made a part of the federal regulatory process.

Mr. Chairman, Title III of H.R. 9 takes a significant step forward in addressing many of the short-comings of current environmental regulation. Title III requires a more open process, it requires greater use of peer review, and it requires cost-benefit analysis for major regulations.

I believe that Title III of H.R. 9 is a good starting point.

However, we need to go further in setting a new environmental policy agenda for the next century, and that is why I introduced H.R. 690, The Risk Assessment and Cost-Benefit Analysis Act of 1995. H.R. 690 includes a number of provisions to supplement and complement title III.

The backbone of H.R. 690 is prioritization — let's tackle the worst problems first. Environmental regulations are costing the American taxpayer over \$130 billion annually. I don't know if that is too much or too little, but we do need to make sure that the money is spent wisely. Like any idealist, I would like to address every environmental and health problem we have, no matter what the magnitude. As a pragmatist, however, I know that cannot be done. In the real world of limited resources, we have no choice but to establish priorities, based on sound data and common sense. H.R. 690 requires federal agencies to focus their monetary and regulatory clout on the risks that pose the greatest dangers to human health and the environment. Tackling the worst first will ensure that we get the biggest bang for the buck, and will help to eliminate intrusive and unwarranted regulations that tinker at the margins of environmental problems.

The "Contract with America" calls for a smaller, smarter federal government.

H.R. 690 responds to that challenge by requiring government to be more efficient and

accountable in protecting citizens from environmental and health risks. H.R. 690 requires the Office of Science and Technology Policy to oversee interagency coordination of risk assessment procedures in order to optimize the use of limited resources, stop unnecessary government duplication, and enhance interagency communication and practices. It also requires OSTP to establish mechanisms for greater communication on risk assessment issues between federal and state regulatory agencies, and periodically to assess the effectiveness of the new way of doing business in a report to Congress. This will help us achieve the goal of the Contract for government to work smarter, quicker and cheaper.

The science supporting risk assessment is not static. Federal agencies must acknowledge in a timely manner the need to consider the impact of new information and scientific understanding on previously conducted risk assessments. To ensure that relevant new information is fully considered, H.R. 690 requires each affected agency to set up a formal process, including peer review and public comment, for consideration of new information on previously issued risk assessments.

H.R. 690 requires OSTP to prepare an annual State of the Environment report. It's time we take a hard look at how effectively we are managing our environment. We need to institute a process that will allow us to ensure that our objectives are targeted and achieved. I view the report as an environmental audit. Under my proposal, OSTP annually would review regulatory actions taken by the government and would tell us if we are reducing risk effectively and efficiently. I believe that the annual report is the kind of information Congress needs if it is to make wise changes in setting environmental policy goals.

As I have stated earlier, I have crafted my legislation to meet the goals of the Contract With America. In a few instances my bill takes a different approach to meeting those goals. In light of the testimony heard this week in both this committee and in the Commerce Committee, I would urge members to look at the way my bill deals with peer review and judicial review before the mark up on these vital issues begin.

Making the risk assessment process more open and accountable is the first step in reforming existing environmental laws. However, it is not the silver bullet that many people would like it to be. A good portion of the blame for ineffective and wasteful regulations must fall on us — the U.S. Congress. We have too often responded to environmental problems by legislating fixes that are not based on sound scientific principles of risk. It is vital that as Congress begins to reauthorize the major environmental statutes it does not overlook the hard work done by this committee to bring good science into the process.



February 2, 1995

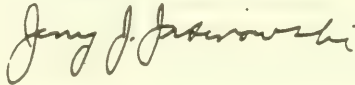
The Honorable Dick Zimmer  
U.S. House of Representatives  
228 Cannon House Office Building  
Washington, DC 20515

Dear Mr. Zimmer:

I am writing on behalf of the Alliance for Reasonable Regulation (ARR). ARR is a broad-based coalition of manufacturers, business, industry, and other organizations dedicated to the enactment of legislation that will require the use of sound science, risk assessment, and sound economics in regulatory decisionmaking.

ARR and its membership -- which now includes more than 1000 organizations -- believes that the environment and people's health and safety can be more effectively protected through prioritization of risks. Your bill, H.R. 690, the Risk Assessment and Cost-Benefit Analysis Act of 1995, includes provisions requiring the use of comparative risk analysis for priority setting purposes. The ARR strongly supports this concept, and we would like to work with you to ensure that this concept is included in any risk legislation passed by the Congress.

Sincerely,



Jerry J. Jasinowski  
President  
National Association of Manufacturers  
Chairman  
Alliance for Reasonable Regulation



CHEMICAL MANUFACTURERS ASSOCIATION

February 2, 1995

The Honorable Dick Zimmer  
U.S. House of Representatives  
Washington, DC 20515

Dear Mr. Zimmer:

As you know, the Chemical Manufacturers Association has a strong interest in risk legislation currently before Congress. CMA believes that efforts to properly assess, prioritize, and manage risks to human health, safety, and the environment are fundamental to regulatory reform. You have long advocated this kind of approach, and we appreciate all of your efforts.

CMA has read with interest your bill, H.R.690, the Risk Assessment and Cost-Benefit Analysis Act of 1995. The bill aims to improve estimates of risk, require analysis of the costs and benefits of major rules, and improve the peer review process. These are the kinds of topics that should be addressed by risk legislation.

One part of the bill that CMA is particularly interested in is Section 4, which calls for the use of comparative risk analysis for priority setting purposes within federal agencies and departments. This kind of priority setting would manifest itself through budget, strategic planning, and research activities. CMA strongly supports this concept, and we want to work with you to see that Congress passes legislation that has this requirement.

Sincerely,

A handwritten signature in dark ink, appearing to read "Timothy F. Burns", written over a horizontal line.

Timothy F. Burns  
Vice President,  
Federal Government Relations

The CHAIRMAN. Thank you, Mr. Zimmer.  
Mr. Mica.

**STATEMENT OF THE HON. JOHN L. MICA, A REPRESENTATIVE  
IN CONGRESS FROM THE STATE OF FLORIDA**

Mr. MICA. Mr. Chairman and Members of the committee, thank you for the opportunity to testify on risk and cost-based environmental decision-making today, particularly with respect to the provisions of the Republican Contract.

Let me say, I strongly endorse Title III of the Contract and have worked during the last couple of years to ensure that the principles of sound risk and cost-benefit analysis are passed and included in the legislation of this Congress. Some of you know the history of my participation, having served on Government Operations, heard the horror stories from business, industry, from local governments, and even from EPA's Inspector General about the mismanagement, lack of direction, lack of focus. And I was convinced that something needed to be done.

As we all know, now, I was rejected in my attempts as I tried to elevate EPA to a Cabinet level position. And we took our fight to the Rules Committee. They rejected us. We took it to the Floor and we won there. We not only won on that vote on February 2nd, 1994, we won in every succeeding vote and by increasingly greater margins because the Congress became educated about the need to include risk assessment and cost benefit in the way we pass regulations in this Congress and for the country.

Despite the House's inability to finalize action on risk assessment legislation during the 103d Congress, we really have a historic opportunity before us today to help some of these regulatory nightmares and the procedures that have been imposed not only by Congress, but also by the administrators.

The legislation included in Title III of the Republican Contract will—I would like to show today how it will solve some of the problems that you have heard of. And I'd like to illustrate some of the absurd manner in which we regulate risk today. This cup of coffee, and some of you may have had a cup of coffee this morning, contains more than a thousand chemicals. More than half the chemicals that have been tested, 19 of 26, are shown to produce cancer in rats in high doses. So there are more carcinogens in a single cup of coffee than potentially carcinogens in pesticide residues that we eat each year.

This does not mean that coffee is dangerous. But that some animal cancer tests and worse case risk assessments end up blowing things way out of proportion. That's why the language in Title III of our legislation in the Contract of America requires Federal agencies to provide, quote, best estimates of risk. And that's a very critical part of these provisions.

Also, the language requiring an agency to place the risk in context by comparing the risk with three other risks that are familiar to the general public must be passed so that we can begin to focus on risk that should be set as priorities. People are tired of seeing millions and millions of dollars and taxpayer dollars in fact chasing insignificant risks.

Another situation that Title III will eliminate was brought to our attention by a Supreme Court Judge Breier. Basically some of you are familiar with that. He said, "Why should we be cleaning up dirt where children can eat it?" Our language in the Contract requires that the Agency explain exposure scenarios and use the best estimates, thus shining some light on the ridiculous assumptions that are used today in the current approach to risk assessment.

Finally, let me share something I learned during the debate last year on Superfund. The administration's Superfund bill forced cleanups to be done to meet a one-in-one-million risk standard. Let me tell you what will happen if we don't pass the Contract language to require best estimates and allow for a range of risk. A one-in-10,000 risk is the risk from eating three peanut butter sandwiches a month. Okay. I've got three peanut butter sandwiches here. Or drinking three-and-a-half cups of coffee every month. Here is one cup of coffee.

If we don't pass the bill, we will potentially force EPA to reduce the risk levels from those levels, a risk of one in 10,000, all the way down to a risk of one in a million.

Now, the Assistant Secretary for Environmental Restoration and Waste Management at the Department of Energy stated to a congressional staffer that the one-in-one-million risk is the risk we all have of cancer from getting—the risk we have of getting cancer from sitting under fluorescent lights, which you're sitting under, and I've got here. Okay.

So here we've got three peanut butter sandwiches and a cup of coffee and we've got a fluorescent light bulb. I'm trying to put this in some perspective so you can understand what they're doing to us. So if you object to this language, you could require EPA and the private sector to spend tens of millions of dollars to reduce the risk from a level of eating three peanut butter sandwiches a month down to the level of risk we have from getting cancer from fluorescent lights above our heads. Is that really the way, I ask you, that we want to spend our taxpayer dollars?

Finally, let me for a moment address some of the arguments made yesterday by opponents of this legislation. The administration has stated that our risk cost benefit legislation is, quote, over prescriptive. This, I submit to you, is a little bit like Dr. Kevorkian saying, I only tell my patients to take two aspirins and get some bed rest.

It is ironic that EPA, which has made the regulatory process such a convoluted and bureaucratic art form, would call this legislation excessively prescriptive. Not only is this proposed legislation prescriptive, it is also, I submit to you, what the doctor has ordered.

Another charge leveled yesterday against our proposal is that of micromanagement. Unfortunately, the only solution to bringing the regulatory process under some control may be a dose of micromanagement. Yes, in fact we may establish multiple requirements and we may carefully manage the process by which new regulations are imposed in this legislation. That's because EPA and the Federal regulators in the past have failed to take the steps necessary to ensure rational regulation.

Now we must take steps to ensure the goal of cost-effective regulation. Unfortunately for EPA and the Federal regulators, it may be necessary for them to complete the 23 analytical steps to perform the regulatory impact analysis required in the Contract. Unfortunately, whispering in their ear, chiding them in congressional forums, and pleading with EPA to bring reason into the regulatory process just has not worked. They just don't get it. Their transmitters just don't pick up certain signals.

I submit that our efforts to incorporate and utilize risk assessment in the regulatory process are in fact pro-environmental and this is a pro-environmental action that in fact those who oppose, the protectors who oppose us, are the protectors of the status quo whose incompetent, misdirected, and unfocused approach to our environmental problems squanders limited resources, ignores real problems, artificially drives up costs, misdirects funds, ignores sound science, and often just defies common sense.

We can and we must do a better job to protect our environment, and we can use risk assessment and cost-benefit analysis to achieve that goal.

So with those comments, Mr. Chairman, and I have some more which I would like to submit for the record, ask unanimous consent that we submit those, I offer this testimony, and also this common sense approach.

[The prepared statement of Mr. Mica follows:]

STATEMENT OF HONORABLE JOHN L. MICA  
February 3, 1995  
Hearing before the Committee on Science

\* Mr. Chairman, members of the Committee, thank you for the opportunity to testify on risk and cost based environmental decisionmaking, particularly with respect to the provisions in the Republican Contract. I strongly endorse Title III of the Contract and have worked since last year to ensure that principles of sound risk assessment and cost/benefit analysis are passed.

\* During the 103rd Congress, I served as a member of the House Government Operations Committee, now known as the Government Reform and Oversight Committee. It was during my service on that Committee last year that I listened to numerous stories from constituents, business, industry, and even the Inspector General of EPA about EPA's complete lack of focus and inability to set environmental priorities. After hearing of the disarray and misdirection I was convinced that we needed some legislative mechanism to make sense of the mess Congress and EPA had created. That's why after being rejected by my Committee and the Rules Committee, I took my risk assessment/ cost-benefit analysis amendment to the House floor. On February 2, 1994 the House spoke clearly by a vote of 227-191 saying that they did not want to discuss elevating EPA to cabinet status unless some risk assessment/cost-benefit language was included. In every succeeding vote the House approved by increasing margins risk assessment provisions.

Despite the House's inability to finalize action on risk assessment legislation during the 103rd Congress, we now have an historic opportunity to pass legislation which can help end some of the regulatory nightmares that have tied up business, industry, and local governments in knots. That legislation is Title III of the Republican Contract. Today I would just like to share with you a few examples which I believe crystallize the need for this legislation. Let me illustrate some of the absurd manners in which we regulate risk.

\* The cup of coffee you may have had this morning contains more than 1,000 chemicals. More than half of the chemicals that have been tested (19/26) are shown to produce cancer in rats at high doses. So, there are more carcinogens in a single cup of coffee than potentially carcinogenic pesticide residues we eat in a year. This DOES NOT MEAN coffee is dangerous, but that some animal cancer tests and "worst-case" risk assessments end up blowing things way out of proportion. That's why the language in Title III of the GOP Contract requiring federal agencies to provide "best estimates" of risk is critical.

Also, the language requiring an agency to place the risk in context by comparing the risk with 3 other risks that are familiar to the general public must be passed so that we can begin to focus on risks that should be priorities. People are tired seeing millions of taxpayer dollars chasing insignificant risks.

\* Another situation that Title III will eliminate was brought to our attention by Supreme Court Judge Stephen Breyer. He said that "it took 10 years of litigation to settle the last bit of clean-up at a New Hampshire toxic waste dump, deciding whether to burn contaminated soil so it would be clean enough for children playing there to EAT the dirt 245 days a year. Our language in the Contract requires the agency to explain "exposure scenarios", and use best estimates thus shining some light on some of the ridiculous assumptions that are used in some of these risk assessments.

Finally, let me share something I learned during the debate last year on Superfund. The Administration's Superfund bill forced cleanups to be done to meet the 1 in 1,000,000 risk standard. Let me tell what will happen if we don't pass the Contract language to require best estimates and allow for a range of risk. A 1 in 10,000 risk is the risk from eating 3 peanut butter sandwiches a month or drinking 3 1/2 cups of coffee every month.

If we don't pass this bill, we will potentially force EPA to reduce risk levels from those levels (a risk of 1 in 10,000) all the way down to 1 in 1,000,000. Now, the Assistant Secretary for Environmental Restoration and Waste Management at the Department of Energy has stated to Congressional staff that the 1 in 1,000,000 risk is the risk we all have of getting cancer from sitting under fluorescent light bulbs.

So if you object to this language, you could require EPA and the private sector to spend tens of millions of dollars to reduce the risks from the level of eating 3 peanut butter sandwiches a month down to a level of the risk we have of getting cancer from the fluorescent lights now above our heads. Now, is that how we want to spend taxpayer dollars???

Finally, let me for a moment address some of the arguments made yesterday by opponents of this legislation. The Administration has stated that our risk/cost-benefit legislation is quote "overprescriptive." This is like Dr. Kevorkian saying "I only tell my patients to take two aspirins and get some bed rest."

It is ironic that EPA which has made the regulatory process such a convoluted and bureaucratic artform would call this legislation "excessively prescriptive." Not only is this proposed legislation prescriptive, it is also what the doctor ordered.

Another charge leveled against our proposal is that of "micromanagement." Unfortunately, the only solution to bring the regulatory process under control may be a dose of micromanagement. Yes in fact we may establish multiple requirements and we may carefully manage the process by which new costly regulations are imposed. Because EPA and federal regulators in the past have failed to take the steps necessary to ensure rational regulation, we must know take steps to ensure the goal of cost-effective regulation is reached.

Unfortunately for EPA and the federal regulators it may be

necessary for them to complete the 23 analytical steps to perform the regulatory impact analysis required in the Contract. Unfortunately, whispering in their ear, chiding them in Congressional forums and pleading with EPA to bring reason into the regulatory process just has not worked. They just don't get it. Their transmitters just don't pick up certain signals.

I submit that our efforts to incorporate and utilize risk assessment in the regulatory process are in fact a pro-environmental action and that in fact it is those protectors of the status quo, whose incompetent, misdirected and unfocused approach to our environmental problems squanders limited resources, ignores real problems, artificially drives up costs, misdirects funds, ignores sound science and often just defies common sense.

We can and must do a better job to protect our environment.

We can use risk assessment and cost benefit analysis to achieve that goal. With limited federal and taxpayer resources we can and must do a better job in formulating regulations that impact personal property, business, industry and our state and local government.

\* Again, thank you for the opportunity to testify. I urge members of this Committee to act quickly to report Title III of the Contract out of this Committee. This will enable us to finally have the opportunity to vote on this issue on the floor of the House, and to fulfill our commitment to the American people, a commitment to bring them smarter and more effective government regulation.

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The CHAIRMAN. Okay. I thank the gentleman. I assure him that we will include any comments that he or Mr. Zimmer might have additionally for the record. By mutual agreement between Mr. Brown and myself, in order that we can get to the administration witnesses and others, we are not going to ask questions of our colleagues here today. I would only say to you, Mr. Mica, that Mr. Ehlers has sent me a note saying, in light of the time, you might want to share your peanut butter sandwiches with us.

Mr. MICA. Mr. Chairman, I would also like to ask unanimous consent, since these are not typical submissions for the record, that the record would in fact reflect that I brought three complete peanut butter sandwiches, one cup of coffee, and one fluorescent light bulb.

The CHAIRMAN. I was worried about the fact that three Members have left the room since you pointed out that fluorescent lights are a problem.

Mr. MICA. Thank you, Mr. Chairman. Thank you for your leadership on this issue.

The CHAIRMAN. We thank you for your testimony, both Mr. Mica and Mr. Zimmer.

The CHAIRMAN. Let me now call our first panel, who will be the witnesses from the administration. We have with us today Lynn Goldman, the Assistant Administrator of the Environmental Protection Agency; Jack Gibbons, the Director of the Office of Science and Technology Policy; Keith Collins, the Chief Economist of the Office of Risk Assessment, Department of Agriculture; and Bill Schultz, from the Food and Drug Administration.

We would invite you all to come to the table.

As we are doing that, I would ask the witnesses that if they can summarize their testimony in a way that would hold testimony to between five and seven minutes, it would be deeply appreciated by the committee so that all of the Members who have shown great interest here have an opportunity to ask questions. Any remarks that you have beyond your oral testimony, will of course be included in the record. And we would invite you to submit additional material as well as documentation for purposes of the record.

With that, I would ask the Honorable John Gibbons if he would be the leadoff witness.

**STATEMENTS OF JACK GIBBONS, DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY POLICY; LYNN GOLDMAN, ASSISTANT ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY; KEITH COLLINS, CHIEF ECONOMIST, OFFICE OF RISK ASSESSMENT, DEPARTMENT OF AGRICULTURE; AND BILL SCHULTZ, FOOD AND DRUG ADMINISTRATION**

Mr. GIBBONS. Thank you, Mr. Chairman, members of the committee. I very much appreciate being here with you this morning to discuss H.R. 3 and specifically Title III of that act, the title on risk assessment and cost-benefit analysis for new regulation. I have a longer, more detailed testimony which I leave for the record, Mr. Chairman.

The CHAIRMAN. Without objection.

Mr. GIBBONS. The stated goal of Title III is to bring together greater scientific and economic rationality to the regulation of risks

to our health, safety and environment. And the administration clearly, Mr. Chairman, actively supports these goals.

If we need to stipulate this morning that the regulatory system is in need of change and improvement and fixing, I don't think we have an argument. The question is not whether, but how we go about that process. We are working hard to reform government programs, to make them work better and cost less, and we're working hard to streamline government to focus on results rather than trying to devise some kind of one-size-fits-all dictate from Washington. But that means establishing a regulatory system that's fair, effective, and affordable.

Now to that end, the administration I think led the way on risk analysis and assessment in its—in the two short years we've been in business, by issuing in September, 1993, Executive Order 12866, which has to do with regulatory planning and review. That Executive Order requires Federal agencies to use risk assessment to help set and amend regulatory priorities.

Agencies were instructed to propose or adopt regulations only after determining that their benefits justify their costs, and to assure that any regulatory decisions be based on the best reasonably obtained scientific, technical, economic and other kinds of data. In taking those actions, the President recognized that while there is an important role in regulation in safeguarding the health and safety of the environment and American people, and again we have no argument about that I'm sure between us, the government, though, also has a basic responsibility to govern wisely and carefully, regulating only when necessary, only in the most cost effective manner, and on the basis of sound evidence and analysis. And I believe that basic idea again is embodied in the opening paragraphs of Title III.

In the light of our work over the last two years on risk assessment and earlier times that I have spent in that same field when I was at the Office of Technology Assessment and in earlier times, we have reviewed Title III of H.R. 9 pretty carefully and in the hope of being able to move forward very quickly in this important area with you. But unfortunately, I have to say this morning, regretfully, that it is the strong view of the administration that the legislation as currently drafted would neither be fair, effective, nor affordable to the American people.

First, it's too prescriptive and too bureaucratic. H.R. 9 mandates a complicated and inflexible cookbook of command and control procedures for risk and cost-benefit analysis that must be followed by the Federal agencies. Each of these procedures offers the basis for substantial subsequent legal challenges and lawsuits. Specifying detailed procedures for risk assessments, which is a rapidly evolving field itself, could freeze the science and frustrate the adoption of better risk assessment procedures as they are developed.

Secondly, it is applied too broadly and inappropriately. H.R. 9 takes procedures designed for one narrowly focused set of scientific health and safety issues, largely cancer risk assessment, and applies them to a wide range of actions by the Federal Government. As a result, detailed risk assessments would be inappropriately required of such areas as international trade exports and imports, timber sales, patent procedures, just to name a few.

Third, it's too costly. H.R. 9 would create such consuming delays for many activities that the cost of the risk assessment review could frequently exceed the benefit added. As a result, timely responses would be inhibited in cases such as investigations of food contamination, control of agricultural pest infestations, and approval of perishable food products.

Fourth, it provides no support for the kind of underlying science that's so desperately needed if we're going to improve this capability. And I'm sure this committee in particular understands that. Risk assessments are only as good as the scientific data that they are built on.

As you know, garbage in equals garbage out. For risk analysis to be effective as a tool of decision-making then, the fundamental scientific data and analysis must be developed in many areas where it is now lacking. All you have to do is scratch the surface in a number of these critical areas and you find very large unknowns that need to be pursued.

I trust this committee understands the paucity of reliable technical data that are needed to undertake comprehensive risk assessment, particularly if Congress seeks to—is at the same time seeking cuts in resources at the Department of Interior, the Environmental Protection Agency, or other places, that where risk research and analysis is being conducted.

The President's 1996 budget will contain strong support for research programs in support of this kind of research and data collection, and I certainly hope to see this support reflected in your authorizations because I think this committee understands better than most the importance of working with information that can be trusted.

In many cases, the effects of the requirements of Title III, whether taken alone or in conjunction with other elements of H.R. 9, would not be to bring sound science and good analysis to bear on regulation, but to load the regulatory system so much that it can't move forward. Ironically, by creating a legal maze only a bureaucrat could love, it would also make it more difficult for citizens to be heard in the regulatory process.

Rather than cutting bureaucracy, it would expand it. Rather than cutting costs to taxpayers and industry, it would increase them. Rather than streamlining government functions, it would make them more complicated and provide more opportunities for litigation. As is currently written, H.R. 9 would provide, quote, job creation and wage enhancement, end quotes, but I—but it strikes me only for lawyers, lobbyists and bureaucrats.

Mr. Chairman, the well-being of every American does depend on using the best science available to determine health and safety risks where our food, our water, our environment, our safety. On that, we can all agree. But we can also all agree, I believe, that no cold mathematical equation, no rigid regulatory process, can take the place of reason or leadership in making those decisions.

As it's currently written, H.R. 9 does exactly that. In its current form, H.R. 9 is an extreme proposal that would make it more difficult to protect public health and safety and the environment. It would place the safety of all Americans in the hands of recipe-following number crunchers whose idea of public health is the bottom

line on a ledger sheet, the very antithesis of what we all should be seeking. Haste does make waste. And my reading of this bill is that it was prepared in haste and without sufficient understanding of the process of science and analysis.

Given the extremely rapid schedule with which the committee is working, we understand your desire to move quickly, but not so quickly as to compound the flaws and negate the good that is in the present system. We shouldn't be throwing the baby out with the bath water.

Distinguished Members, let us, as Lyndon Johnson once said, let us reason together and act thoughtfully and knowledgeably. I hope that you will not find my words today, Mr. Chairman, intemperate or feel that our analysis of the current bill belies our strong commitment to working with you and the committee on this issue.

The administration deeply shares the goal of better decision-making across the Federal Government, but we do want to see those decisions informed not by inflexible equations and analyses aided and abetted by eager litigants. Americans can and should expect better from their government. I believe that by working together we can craft legislation to accomplish these goals and we stand ready and eager to work with you in that direction. We are ready to enact risk legislation that is fair, effective and affordable.

Thank you, Mr. Chairman. I appreciate the time before you this morning. Be happy to answer questions when they come.

[The prepared statement of Mr. Gibbons follows:]

EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF SCIENCE AND TECHNOLOGY POLICY  
WASHINGTON, D.C. 20500

**STATEMENT OF DR. JOHN H. GIBBONS  
DIRECTOR  
OFFICE OF SCIENCE AND TECHNOLOGY POLICY  
EXECUTIVE OFFICE OF THE PRESIDENT  
BEFORE THE  
COMMITTEE ON SCIENCE  
U.S. HOUSE OF REPRESENTATIVES**

**February 3, 1995**

Good morning, Mr. Chairman and Members of the Committee. I am pleased to be here today to discuss with you Title III, on "Risk Assessment and Cost-Benefit Analysis for New Regulations," of H.R. 9. The Administration looks forward to working with you on these important specific subjects, and on improving the regulatory system in general, in the coming weeks and months.

Title III's stated goal is to bring greater scientific and economic rationality to the regulation of risks to our health, safety, and environment. It recognizes that "[e]nvironmental, health, and safety regulations have led to dramatic improvements in the environment and have significantly reduced human health risk." At the same time, it finds that "[t]he public and private resources available to address health, safety, and environmental concerns are not unlimited; those resources need to be allocated to address the greatest needs in the most cost-effective manner,... so that the incremental costs of regulatory options are reasonably related to the incremental benefits." To this end, it proposes to bring scientifically objective information on health, safety, and environmental risk to bear on regulatory problems "in order to provide for sound regulatory decisions and public education." The result, it finds, will be to "allow for public scrutiny and [to] promote quality, integrity, and responsiveness of agency decisions."

The Administration actively supports these goals. We have spoken often of the need for risk and cost/benefit analysis, for good data and sound analysis, and for an open and transparent process. In fact, we have already done a great deal to encourage and enhance

these efforts in diverse federal agencies. The Executive Order on Regulatory Planning and Review (No. 12866), which the President signed on September 30, 1993, represents a key milestone in our efforts to improve governance. The Executive Order recognizes that there is an important role for regulation in safeguarding the health, safety, and environment of the American people. At the same time, it emphasizes that government has a basic responsibility to govern wisely and carefully, regulating only when necessary and only in the most cost-effective manner.

The Executive Order requires agencies to propose or adopt regulations only after determining that their benefits justify their costs, and that the rules themselves are developed according to sound regulatory principles, including the use of market-based incentives.

It also requires agencies to base their regulatory decisions on the best reasonably obtainable scientific, technical, economic, and other data. And it specifically calls for the use of risk analysis in regulatory decision making. The Executive Order states that “[i]n setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.” It also asks agencies, in developing regulations, to consider “how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency.”

The Executive Order established the Regulatory Working Group which serves “as a forum to assist agencies in identifying and analyzing important regulatory issues (including... the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making...).” The Regulatory Working Group subcommittee that I chair has been focusing on the issue of risk analysis, and it recently produced a set of principles to give agencies more specific guidance in assessing, managing, communicating, and prioritizing risks.

The Administration endorses efforts to promote the appropriate use of risk and cost/benefit analysis as part of the Federal rulemaking process. Risk and cost/benefit analysis are particularly valuable tools in helping agencies make decisions to reduce risks to health, safety, and the environment in a sensible and cost-effective manner. The Administration, therefore, supports risk and cost/benefit legislation that is fair, effective, and affordable. But we do not support legislation that is likely to burden the regulatory process

with unnecessary, costly, or useless requirements, which H.R. 9 as currently drafted would do.

We also urge caution in the confidence we put into risk and cost-benefit analyses. I am reminded of the saying "garbage in, garbage out." Analyses of this kind are only as good as the data that are available. For example, there are few data available on the toxicological properties of many of the chemicals in commerce. We cannot develop a credible risk analysis in the absence of credible data. On the other hand, when data are well-established, it does not make sense to go through a costly, prescriptive process such as that required in Title III.

We must also bear in mind that it is frequently more difficult to quantify the benefits of an environmental, health, or safety action than to measure its costs. Typically, for environment, health, and safety regulations the costs are concentrated in the near-term, while the benefits are dispersed over time. It might be difficult, for example, to quantify the long-term economic benefits of saving the bald eagle, but virtually all Americans supported efforts to save this national treasure.

Let us not become overly technocratic and assume that we can distill difficult public policy decisions down to one-size-fits-all, prescriptive procedures, or simple equations. On the other hand, let us ensure that we make full use of science, that we appropriately apply analysis in setting priorities, and that we ensure consistency in analytical procedures where appropriate.

Good judgment and common sense should not be replaced by bureaucratic procedures that appear on their surface to simplify difficult public policy decisions. Let us not be lulled into rigid, technocratic decision making. In the long run, that would be a cold, impersonal, and highly inappropriate dead end that does a disservice to the public who have placed trust in us to protect their health and the environment.

We have reviewed Title III of H.R. 9 carefully and with very much regret conclude that it is not fair, effective, and affordable; nor does it live up to its own professed standards of regulatory efficiency and cost-effectiveness. As drafted, Title III is an extreme measure, fraught with unintended consequences, that would only exacerbate the problem it ostensibly seeks to address: an inflexible regulatory system insufficiently tuned to costs. Indeed, many

of the criticisms to which our current regulatory system is subject — that there are too many requirements, many of which are too burdensome; that it fails to tailor regulations to the particular characteristics of the regulated community; that it relies on command and control rather than economic incentives; that it requires excessive paperwork; that it produces rules that are difficult to understand — can be leveled against the approach taken in Title III. The bill's provisions apply too broadly, are too prescriptive and too costly, and would create endless analytic loops and excessive opportunities for litigation. I have heard it described as a “lawyer's full employment act.” Let me be more specific.

Title III creates risk assessment, risk and cost/benefit analysis, and peer review requirements for agencies in connection with regulatory programs designed to protect “human health, safety, or the environment.” These terms, which at their core are an apt description of a category of well-defined regulatory programs, as used in the bill would apply to a large number of agency activities. For example, do you really want the Department of Commerce to have to go through the Title III risk assessment, certification, and peer review process before issuing a rule to open fishing season at a particular set of fisheries? The Internal Revenue Service before it revises its income tax regulations concerning the electric vehicle or the alcohol fuel tax credit? The Department of Transportation before it issues mirror requirements to help school bus drivers see children near the bus? The Department of Interior before it authorizes the seasonal hunting of certain migratory birds otherwise illegal to shoot?

In the past, Congress has spoken about factors that agencies are to consider in issuing health, safety, and environmental regulations, and it has done so clearly. It has, on occasion, explicitly or implicitly precluded the consideration of cost and risk in decision making. The Delaney Clause and technology-based standards are two examples. In those instances, what purpose is served by requiring, as per Title III, an agency to perform an elaborate and costly risk assessment (including a discussion of laboratory and epidemiological data and of comparative animal and human physiology, routes of exposure, bioavailability, and pharmacokinetics; a presentation of plausible and alternative assumptions, a full description of the model used in the risk assessment and the assumptions incorporated therein, and a indication of the extent to which this model has been validated by empirical

data; a statement of the reasonable range of scientific uncertainties; a "best estimate" of risk; an explanation of the exposure scenarios employed by the risk analysis; comparisons to other health risks; and an analysis of any substitution risks), to assess costs and benefits, to make the required certifications, to conduct an external peer review, and to prepare a written response to the peer review panel's comments? In such instances, we believe Title III would serve only to increase costs dramatically and delay agency action, just at a time when we all are trying to make governance more efficient and effective.

Even in those circumstances where the underlying statute does not preclude consideration of cost and risk, the requirements in Title III are too broad given the different missions of different agencies. For example, the focus of several of Title III's provisions appears to be on cancer risks. That may be relevant to the Environmental Protection Agency's regulation of toxic chemicals (although certainly not complete in terms of impacts that should be evaluated, such as other health risks, including birth defects, nervous system damage, or reproductive effects, as well as ecological impacts), but does it make sense when evaluating the Occupational Safety and Health Administration's regulation of safety hazards in the construction industry, the Federal Emergency Management Administration's regulation of fire and flood hazards, or the Department of Transportation's side impact standards for auto safety? What purpose would be served by requiring the Federal Aviation Administration, in determining whether an aircraft should be grounded because of icing problems, to "explain the exposure scenarios" used in its risk assessments and go into lengthy deliberations and court challenges before it can take action? Or by requiring the Department of Commerce, in regulating fisheries, both to compare the risk of fish depletion to six other risks and to issue a statement of the human health risks its regulation could potentially create?

The excessive breadth of Title III is also reflected in the many ways its provisions would be triggered. For example, in Subtitle A, under section 3103, every time an agency prepares a risk assessment (except in emergencies or for some screening analyses), it would have to do so according to detailed risk assessment procedures. And section 3105, which dictates how risk characterizations are to be made, applies every time an agency makes a document characterizing risks available to the public. There is no distinction based on the

significance of the decision or the purpose of the risk assessment. But does it really make sense to go through the full drill in every instance? Would there not be some cases where the cost of following these detailed procedures would overwhelm the benefit to be derived from the risk assessment?

We have noted that Subtitles B and C, which require risk and cost/benefit analyses, and peer review, respectively, do include dollar thresholds. As drafted, agencies would have to do risk and cost/benefit analyses for any regulation with an annual effect of more than \$25 million. To trigger a mandatory peer review, the threshold is \$100 million — unless it is a final rule under section 3201(a)(5)(A) and the agency has received relevant information from interested parties, in which case the threshold falls to \$25 million. And Title VII requires a risk analysis if the annual effect is more than \$1 million for any person or affects more than 100 persons.

Back in 1993, in preparing Executive Order 12866, the Administration consciously selected \$100 million as the threshold for requiring a cost/benefit analysis, having determined that the resources devoted to regulatory analysis should be commensurate with the significance of the regulatory decision to be made. There were suggestions at the time that the threshold should be higher, since 12 years earlier President Reagan's Executive Order on regulatory review had drawn the line at \$100 million. Now Title III would set the threshold at a quarter of the level President Reagan selected 14 years ago.

Risk assessment is a relatively young field, and methods are continuously being refined. The recent report of the National Research Council, *Science and Judgment in Risk Assessment*, supported the general procedures for conducting risk assessments at the Environmental Protection Agency and elsewhere. It identified weaknesses in the current system and offered a number of helpful recommendations to address them. Federal agencies are now responding to these recommendations. Unfortunately, the prescriptive measures called for in Title III would run rough-shod over this positive evolutionary process. The National Academy of Sciences has been working to advance methods to evaluate risk for more than a decade and has produced considerable thoughtful guidance. EPA and other agencies are constantly working to improve their risk assessment methodologies. Federal

statutes that prescribe scientific procedures in excessive detail treat science and analysis as a static rather than dynamic process.

Congress and the Executive branch should foster innovation and progress in the risk analysis area. If risk analysis is to be used in ways that I think we all want it to be, we must support research programs in federal agencies directed to risk assessment and underlying research, using risk in priority setting, and risk communication. This is a rapidly evolving field, and we have much to learn.

Through the National Science and Technology Council we have developed a strategy for risk-related research, and federal agencies are working to direct their research and budget priorities toward the objectives identified in the strategy. H.R. 9 places major requirements for risk analysis on more than a dozen federal agencies, but it includes no provisions to foster aggressively a credible scientific base for such analysis. In our view, any legislation in the risk area must include provisions for research and development; otherwise federal decisions will not meet the standards the public — and courts — will insist on.

I would like to point to some specific examples where specific wording in Title III is problematic. Terms such as “scientifically objective and unbiased” and “best estimate” do not have a common definition among risk assessors. The use of these terms in Title III seems to be related to using mid-range, or average, assumptions and default values. This may result in less protection for more sensitive or exposed segments of the public — for example, children, pregnant women, the elderly, the chronically ill, and workers. If our risk analyses in the past were based only on the average adult male, for example, we would not have regulated lead, which can have a major impact on the developing nervous system of young children. We oppose risk methodologies that would minimize or diminish concerns related to our children, pregnant women, the elderly, and others who are often disproportionately affected by environmental, health and safety threats.

The terms of Title III dictate with precision each and every step that an agency is to take. For example, section 3105 tells agencies that any characterization of risk is to describe the subject of the risk characterization, to estimate risks on the basis of a “best estimate,” to state a “reasonable range of scientific uncertainties,” to explain exposure scenarios used in the risk assessment, to make six comparisons (of two different varieties) to other risks with

which the public is familiar and routinely encounters, to include a statement of any significant substitution risks to human health, and to present a summary of any risk assessments submitted by public commenters.

This is quintessential micromanagement and command and control. It tells agencies how to do something — rather than specifying what is to be achieved (or, in regulatory parlance, the performance standard that is to be met). It is process-oriented rather than goal-oriented. But is that not one of the principal legitimate criticisms of our regulatory system — namely, that it relies too heavily on command and control rather than performance standards? Would it not be better to set forth the goals that you want agencies to achieve rather than telling them precisely how to do so? Legislation embodying the performance standard approach would require agencies to use objectively verifiable scientific methods, providing sufficient information so that their scientific analysis could be replicated, to explain and make transparent their assumptions, including who or what is being protected and why, and to provide meaningful explanations of risks, including comparisons relevant to the decision being made and meaningful to the public.

Section 3104(a), which seeks to distinguish scientific findings from policy considerations, and 3104(b)(2) — which requires an explanation of assumptions, an explanation of the basis for any choices, identification of any policy or value judgments that have entered into the analysis, and a description of any model used in the risk assessment and the assumptions it incorporates — represent a promising start in that direction. But requirements that may be valuable on their own can become counterproductive when layered atop other requirements designed to achieve the same end.

It is, therefore, unfortunate that Title III requires so many layers of analysis. Add to the analytical steps and written certifications and explanations Title III would require, the extensive reporting requirements in section 3106 and section 3301(g). Consider: 15 months after enactment, the President would be required to issue guidelines for conducting and a format for summarizing risk assessments; three months later, each agency would have to publish a plan to review and revise its earlier risk assessments; within the following 18 months, each agency would have to provide a report to Congress on the types of policy judgments it had made in its risk assessments. The President, meanwhile, in addition to

reviewing his guidelines every four years, would have to appoint special Peer Review Panels that would conduct — every year — a review of the risk and cost assessment practices of each agency and submit an annual report to Congress. This surely is not consistent with Title V of H.R. 9, “Strengthening the Paperwork Reduction Act.”

Title III's peer review requirements (Subtitle C) follows the same pattern of excessive prescription and unnecessary layering. Subtitle C starts off promisingly enough. Each agency, section 3301(a) states in part, “shall develop a systematic program for peer review of risk assessments and economic assessments used by the agency... consisting of independent and external experts who are broadly representative and balanced to the extent feasible,” and “may provide for differing levels of peer review depending on the significance or the complexity of the problems or the need for expeditiousness.” That seems adequate to do the job, as well as sensitive to the notion that the amount of analysis devoted to a regulation should be proportional to its significance. But then section 3301(b) and (c) requires that each agency describe precisely what a peer review panel must do, how the agency shall respond to the peer review, and even which of the panel's comments must be published as text and which as appendix. This is micromanagement at its worst. Why couldn't agencies be required simply to have a peer review plan, tailored to the types of risks they address and the relevant sciences that are involved? The plan could be made available to the public and could indicate which type of risk assessments would be subject to peer review, whether external or internal.

Unfortunately, Title III not only emulates some of the most undesirable approaches used in our current regulatory system, but also creates seemingly endless analytic loops that could introduce additional inefficiency and delay in the rulemaking process. Section 3201(a)(3), for example, requires that each proposed or promulgated rule be accompanied by, among other things, a statement of “other human health risks potentially posed” by the rule and each regulatory alternative to it. This requirement is wholly open-ended: must the agency list all health risks each alternative could create, no matter how unlikely or remote these risks may be? Then consider that a statement of other health risks is itself a risk characterization and consequently must also be prepared and presented according to the detailed requirements set out in other parts of Title III.

The objective of risk legislation should be to improve the regulatory process, not to create unproductive paper record requirements, extra bureaucratic costs, or additional opportunities for litigation. Title III, however, does the latter. Because Title III does not preclude judicial review, the Administrative Procedure Act, which authorizes judicial review of final agency action, would apply. Section 3301(e), moreover, explicitly makes peer reviews and agency responses to peer reviews part of the administrative record “for purposes of judicial review of any final agency action.” Presumably then, both an agency’s compliance with each of the bill’s procedural steps and the content of the agency’s risk and cost/benefit analyses could become the subject of court challenges once a final rule is promulgated. That would be unfortunate, as it would likely require the Federal agencies to spend added time satisfying (with the extra margin needed to ensure affirmation in court) each of Title III’s many steps, and producing even more paper and an even larger record — efforts that would take a good deal of time and resources without producing sounder regulations.

Before closing, it is important to note that although Title III alone is before this Committee, it is only one piece of a larger bill. As you consider testimony on Title III, the Judiciary Committee is about to take up Title VII, “Regulatory Impact Analyses.” Title VII requires each agency, before proposing or issuing a regulation, to go through 23 analytical steps to conduct the regulatory impact analysis; such an analysis would be required for any proposed rule that would require the expenditure of more than \$1 million by any single person or affect more than 100 persons. Step six is a statement that describes and quantifies the risks to human health or to the environment; step seven is a cost-effectiveness requirement; step eight is a description of alternative approaches considered by and suggested to the agency; and steps 10 and 11 require an estimate and evaluation of costs and benefits. These are the same analyses that are to be performed under Title III. Is the agency to conduct these analyses twice? The detailed prescriptions in these two titles differ in conflicting ways, such as their monetary thresholds. We would ask you to consider Title VII carefully when you take up Title III, just as we will ask the Judiciary Committee to consider what is in Title III when it takes up Title VII.

The effect of the requirements of Title III, whether taken alone or in conjunction with Title VII, is not to bring sound science and good analysis to bear on regulation, but to load the regulatory system so much that it cannot move forward. While substantially retarding our ability to take sensible steps to protect human health, human safety, and the environment, these requirements would create more bureaucracy, more paperwork, and less efficiency in government.

Because it is too broadly applied, too prescriptive, too costly, and too inviting of additional litigation, the risk assessment and cost/benefit provisions of H.R. 9 would cause far more problems than they would solve. It remains my hope, however, that we will be able to work together to help to bring the American people a rational regulatory system that protects our health and safety and the environment on the basis of sound science, without imposing undue costs and burdens.

Thank you, Mr. Chairman. I would be happy to answer any questions you may have.

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The CHAIRMAN. Thank you very much.

Dr. Goldman.

Ms. GOLDMAN. Mr. Chairman, and Members of the committee, I appreciate the opportunity to appear before you today. H.R. 9 is of great significance to us and could drastically alter our ability to protect the health and the environment of the American people.

In considering the legislative proposals currently before you, you will determine whether the citizens of this country can continue to count on the public health and environmental protections that are among the best in the world. You will also decide whether the sound science and analysis underlying these protections will continue to improve, and to incorporate the powerful discoveries of basic research.

We at the Environmental Protection Agency are staunch advocates of sound science and risk assessment and of its appropriate use, along with cost-benefit and other analyses to help us understand problems and to formulate solutions. We do agree that there is a need to improve the quality of the science and the economics used in public health decisions.

For the past two years, EPA has given this issue top priority attention. We agree that risk assessment should use the best information available, apply it in an objective manner, and that the science used in the risk assessment should undergo appropriate scientific peer review.

During these two years, we have established a new policy that requires scientific peer review of all major original science products, not only risk assessments, and we will shortly publish a new policy to improve our risk characterizations. It is important to note that, as the National Academy of Sciences recently said, risk assessment is a set of tools, not an end in itself.

Risk assessment and cost benefit analyses are only valuable to the Nation if they are able to serve in making decisions fair, effective, and affordable. However, H.R. 9 cannot be fair, effective, and affordable if it revokes the contract of health and environmental protection that the Congress has with the American people.

H.R. 9 cannot be fair if it lessens health and environmental protection and stifles innovation. It cannot be fair if it forces us to reduce the protection we provide to our children by imposing unnecessary and time-consuming bureaucratic delays. It cannot be effective and affordable if it makes programs inefficient and more costly to the public and to the regulated community. It cannot be affordable if it encourages endless litigation.

Titles III and VII together may impose rigid or even scientifically unsupportable requirements for the ways we conduct analyses. These roadblocks could prevent action for which a full set of information is not available. For example, pesticide registrations weigh costs and benefits by exercising sound scientific judgment and reason.

H.R. 9 subjects this science to judicial review, which we believe is inappropriate. Science shouldn't be decided by the courts. Moreover, data are often incomplete for a pesticide-developmental effects in children, reproductive effects in men and women, neurotoxic effects, and ecological effects of many kinds, may be associated with the use and these cannot be fitted neatly into rigid equations due

to lack of data and scientifically accepted techniques for extrapolation and quantitative assessment.

Today the industry spends approximately \$5 million for each new pesticide registration to bring to the market. H.R. 9's prescriptive requirements could increase these costs. There are other examples where delays could be created. Delay on our proposed derogatorily action that will save the economy \$2 to \$6 billion and control costs of PCBs, delays in premanufacture review of new chemicals that currently take 90 days, delays in Superfund cleanups and decisions.

The proposal may also be interpreted as allowing risk litigation about science before any final agency action is taken, or even if no agency regulation is ever contemplated. The prescriptive nature of H.R. 9 may invite courts to decide complex scientific issues about changes in risk assessment science and views of appropriate models, assumptions, and interpretations of empirical data.

We only need to look to the Delaney Clause and court actions to see a real example of statutes in the court attempting to interpret those statutes, preventing the incorporation of new science and standing in the way of common sense approaches.

In closing, let me stress once again that EPA is the world leader in the use of risk assessment as an important tool. We do thousands of risk assessments every year and have done so for more than 20 years. We have continuously invested resources to improve our risk assessments. Over the years, we have published guidelines in many areas of risk assessment. This compendium of guidance is unique in the world in its scope and utility for scientists, policymakers, and the public.

In summary, we are absolutely committed to common sense and scientifically sound public health and environmental protection programs. We believe that H.R. 9, as written, will impede rather than help meet these goals. We would like to work with you to give the American people the sound science, wise decisions, and clear understanding that are the stated purposes of H.R. 9.

Thank you.

[The prepared statement of Ms. Goldman follows:]

**STATEMENT OF  
DR. LYNN GOLDMAN  
ASSISTANT ADMINISTRATOR  
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES  
U.S. ENVIRONMENTAL PROTECTION AGENCY  
BEFORE THE  
COMMITTEE ON SCIENCE  
U.S. HOUSE OF REPRESENTATIVES**

**February 3, 1995**

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Mr. Chairman and Members of the Committee. I appreciate the opportunity to appear before you today. HR 9, the Job Creation and Wage Enhancement Act of 1995, is of great significance to us and to other Federal agencies, and could drastically alter our ability to develop reasonable mechanisms for protecting the health and environment of the American people. In considering the legislative proposals currently before you, you will determine whether the process by which the Agency makes public health and environmental protection decisions rests on sound science and workable procedures. You will also decide whether the scientific and other analyses underlying our understanding of the effects of human activity on health and the environment will continue to improve and incorporate the powerful and currently astounding discoveries of basic research about the biology of living systems.

We at the Environmental Protection Agency are staunch advocates of the science of risk assessment and of its appropriate use along with cost benefit and other analyses that assist us to understand problems and to formulate solutions. We do agree, however, that there is a need to improve the quality of the science and the

economics that go into public health decisions. For the past two years the EPA has given this issue top priority attention and has taken a large number of steps to accomplish this goal, and to chart the course for the future. We agree that risk assessments should use the best information available, apply it in an impartial and objective manner, and that the science used in the risk assessments should undergo appropriate peer review. Among other steps, during these two years we have established a new policy at EPA that requires impartial peer review of all major original science products — not only risk assessments — and will shortly publish a new policy to improve our risk characterizations.

It is important to note that, as the National Academy of Sciences recently said, "Risk Assessment is a set of tools, not an end in itself." Risk assessment analyses are only valuable to the Nation if they are able to serve in making actions fair, effective and affordable. This is the measure of national value that the Congress should also use for HR 9 provisions that reconstruct and apply these analyses.

In our day to day activities, we use risk assessment tools in analyses ranging from small screening analyses for priority setting to large scale air transport modelling of pollutant dispersion that requires massive parallel array computing. We analyze issues such as whether a chemical may cause cancer, neurotoxicity, reproductive or developmental effects in humans or ecological communities. We examine phenomena ranging from eutrophication of lakes to effects of the Mississippi River floods on

mobilization of contaminants from flooded soils, to movement of chemicals through complicated geological formations. We discover new questions and answers and use the new science coming from basic science to change our views and methods as we go. We administer statutes that contain about 30 different provisions requiring hazard, exposure, or risk findings for different purposes. These include ranking chemicals and sources, registering pesticides, inventorying emissions, deciding on water and air pollution criteria, cleaning up sites, requiring toxicity testing, and more. We generate and communicate about analyses with the scientific community, state and local governments, and international organizations continuously and on a very large scale. Virtually every analysis we do is available to the public and subject to the Freedom of Information Act. Whether we are able to continue this level of activity and public engagement and to constantly improve the science of risk assessment is a question before you now.

In considering the future of health and environmental protection activities, we support several goals and caution against proposals that would unintentionally defeat them.

As Administrator Browner said at the hearing of the Science Committee on January 6, we will support legislation that says that risk assessments should provide both decision makers and the public with a clear and meaningful understanding of the risks that will be addressed by our actions, as well as an understanding of the assumptions and uncertainties inherent in the assessments. Moreover, we agree that the science used

in risk assessments should undergo appropriate peer review. We have taken steps to assure that our risk assessments meet these goals.

H.R. 9 appears to create many new opportunities for litigation about the content or conduct of scientific or other analyses prior to the judicial review already provided under the Administrative Procedures Act and EPA statutes. It appears to move questions about scientific procedures and methods into the courtroom, and would freeze scientific progress and add yet another layer of contentious litigation to the rulemaking process, and delay needed environmental protection action.

We share the stated Congressional goals of good science and communication and appropriate peer review. Legislative proposals that establish goals and benchmarks for effective and efficient decision making are appropriate. On the other hand, proposals to control the substance and conduct of scientific analyses, and to create costly processes that would add costs for regulated businesses and public health and our environment, could defeat the goals they are intended to achieve. Good science, wise decisions, and clear and fair communication could become frozen science, delayed decisions, and excessive paperwork.

The provisions apply the same requirements for content and presentation of risk analyses to everything from a major rulemaking endeavor to a minor exemption process. An exercise to set priorities among risks for devoting further resources

becomes equal in documentation to a national rule. Since screening analyses are subject to Freedom of Information Act requirements to make Agency records available to the public, any internal screening analysis that makes a positive statement about risk is subject to HR 9 requirements and litigation, even a letter to another Federal agency or to the Congress that discusses a potential risk problem. This is not an investment of resources that is consistent with the importance of the decision being made. It does not contribute to making decisions more fair, effective, or affordable.

The prescriptive nature of HR 9 may invite courts to decide complex scientific issues, such as how to determine a central estimate of risk for the endangerment of a fishery, or whether an alternative model is appropriate for consideration. There is a real danger that, if we are not careful, changes in risk assessment science and views of appropriate models, assumptions and interpretations of empirical data may soon be judged by case law, not by scientists. This would make it extremely difficult for risk assessments in the future to reflect improvements in the science made after any particular judicial decision. We need only look to the Delaney Clause and court actions to see a real example of statutes and courts preventing the use of new science, and standing in the way of common sense approaches. While it is most likely these concerns would apply in the context of final Agency actions, there is some concern that — based on existing precedent — the proposal can be interpreted as providing for risk assessment-related litigation before any final Agency action is taken, or even if no

Agency action is ever taken. Some courts have even found that risk assessments themselves constitute sufficient Agency action to trigger judicial review.

HR 9's requirements for considering and discussing selected items in all risk analyses are operationally equal to adding more statutory findings to all of the 30-odd risk findings already in existing statutes. This will have important unintended consequences, as it will take longer to take public health protection actions because it adds more analyses; and those analyses appear to be subject to litigation. It will not only make regulatory action more difficult, but also make deregulatory action equally difficult. For example, in my office we are working on a deregulatory action that will save the economy 2 to 6 billion dollars in control costs of PCBs (PolyChlorinated Biphenyls). Because there are positive risk findings about PCBs discussed in the action, we are concerned that the action will be delayed under HR 9 to the same extent as a new regulatory action. For another example, the current 90-day premanufacture review process under the Toxic Substance Control Act — which operates efficiently even when positive indications of risk are found — may become a thing of the past, and create additional data provision costs for those who would like to market new products. A third example relates to the unclear impact of this bill on Superfund. This Administration is committed to making Superfund more effective and efficient. There was broad consensus last year among government, industry and environmental public interest groups that Superfund could be made more efficient. We are concerned that HR 9 does not facilitate this goal — all Superfund risk assessments fall under these

requirements, and all clean-up decisions will be reviewable against the cost benefit standard. It is not clear how HR 9 is intended to work along with the existing, or a new reintroduced statute, particularly the proposals from last year designed to diminish — not increase — transaction costs.

Title III and Title VII together may create large roadblocks to any action for which the data for a full cost benefit analysis are not available. For example, pesticide registrations are regulations for chemicals designed to kill pests and weeds — farmers need these tools — but we don't want people or the environment to be harmed by their use. We strike this balance by weighing information under the pesticide law's cost benefit standard and by the exercise of scientific judgement and reason. HR 9 subjects this science to judicial review — which we believe is inappropriate.

Moreover, data are often not available for environmental exposures involving critical health and ecological effects. Developmental effects in children, reproductive effects in men and women, neurotoxic effects, and ecological effects of many kinds that may be associated with pesticide use cannot be neatly fitted into rigid equations due to lack of data and scientifically accepted techniques for extrapolation and quantitative assessment. Industry currently spends five million dollars for each new pesticide registration to provide data to us. Even then, we still don't have the scientific techniques to quantify non-cancer or ecological effects.

Finally, many of the statutory provisions administered by EPA, as well as provisions administered by other Federal agencies, do not currently permit cost benefit to be the criterion by which a standard is set, or a decision made. One example is that of the National Ambient Air Quality Standards under the Clean Air Act which are based on health and environmental considerations alone — "...protect public health with an adequate margin of safety". Yet, HR 9 appears to require the Agency to certify that these standards produce benefits that justify the costs, and allows judicial review of that certification. Moreover, the Act is ambiguous as to whether it is intended to supersede these underlying statutory standards with a new standard of cost benefit.

We are committed to the goals I set out above. We believe that we can work with you to give the American people the sound science, wise decisions, and clear understanding that are the stated purposes of HR 9. We are ready to move forward with you to put in place the kind of legislation that will make this happen.

The CHAIRMAN. Thank you, Dr. Goldman.  
Mr. Collins.

Mr. COLLINS. Thank you, Mr. Chairman, Members of the committee. I appreciate the opportunity to be invited today to express the views of the Department of Agriculture on Title III.

At USDA, we strongly support risk assessment as a means to improve delivery of our programs. However, we object to provisions of Title III because of its potentially harmful effects on agricultural trade, agricultural business activity, and related business activity, and because it reduces our ability to protect human health and the environment and creates unnecessary red tape and bureaucracy.

At the Department of Agriculture, we have a very diverse mission, which would be affected by H.R. 9. We must assure an adequate and nutritious diet for vulnerable people through the Food Stamp Program and through other food assistance programs. We're charged with the safety of the Nation's meat, poultry and egg supply.

We must conserve natural resources and protect the environment, while we manage the use of 191 million acres of national forests and grasslands. And we offer a range of financial assistance and technical assistance programs to achieve that as well. We must protect American agriculture and the general public from plant pests and animal diseases.

H.R. 9 prescribes approaches that do not fit a lot of our business. We're involved in the assessment of biological agents and many environmental outcomes. Pathogens in meat or biological agents introduced through farm imports reproduce and they may spread in a matter of hours. Risk changes over time, and it changes over place, as these diseases or pests move through the food chain or move out into farm country.

Risk assessment must be flexible, it must be flexible enough to address these types of hazards and they must allow assessments to be timely and to prevent a threat from growing into an emergency.

Title III could affect many of our programs. Are the added requirements necessary, for example, for making annual benefit level adjustments in the Food Stamp Program? Or are they necessary for rules to change the eligibility criteria for contracts with farmers who voluntarily enter into with us to restore wetlands under our Wetland Reserve Program? Or are they appropriate for the Forest Service's daily notifications to the public of the risk of fire in our national forests?

H.R. 9 could affect USDA's control of pests and animal diseases and increase industry costs. I think an example of that is the Eurasian pine bark beetle, which is now infesting north central States. Recently, one State developed a set of 25 actions that the timber industry was asked to implement. USDA conducted a timely risk assessment that convinced the State that only two to three measures were sufficient to control the pest's spread. A delay in this assessment would have meant more costly controls on the timber and related industries.

Another area where we are concerned is the unintended consequence of H.R. 9 on international agricultural trade. USDA conducts risk assessments for pests and disease of imported plant and

livestock products. We do that for all such products prior to their entry into the United States. Every importation requires a risk assessment or a risk characterization. And that is a public document.

A more time-consuming and bureaucratic process would deprive the importer of product. It could even lead to loss of product, such as rotted fruit. A delay of imports means lost economic activity, lost GDP, and ultimately lost jobs. And under the Uruguay Round, delays that are inconsistent with international risk assessment standards could lead to agricultural trade disputes.

USDA believes in sound science-based risk assessment. Legislation enacted only four months ago mandated the creation of an Office of Risk Assessment and Cost-Benefit Analysis at the Department of Agriculture. That office is mandated to ensure appropriate risk analysis is conducted.

The law provides a balance between prescription and flexibility, which we believe is lacking in H.R. 9. However well-intentioned, H.R. 9 will add unnecessary costs to the taxpayer and result in detrimental effects on the way we manage our programs, which improve the lives of Americans every day.

Thank you.

[The prepared statement of Mr. Collins follows:]

**STATEMENT OF KEITH COLLINS  
ACTING CHIEF ECONOMIST  
BEFORE THE COMMITTEE ON SCIENCE  
U.S. HOUSE OF REPRESENTATIVES  
February 3, 1995**

Mr. Chairman and members of the Committee, I appreciate the opportunity to present the views of the U.S. Department of Agriculture (USDA) on Title III of H.R. 9, the "Job Creation and Wage Enhancement Act of 1995." We strongly support the use of risk assessment and cost-benefit analysis for the efficiency and effectiveness these analytical tools can bring to government programs. However, we object to provisions of this legislation that would have serious effects on the Department's ability to protect human health, safety and the environment, would adversely affect the economic performance of agricultural and other businesses dependent on our programs and would create unnecessary red tape and bureaucracy.

The USDA has a vast mission that includes assuring an adequate and nutritious diet for vulnerable populations through the Food Stamp Program, the Child Nutrition Programs and other programs. We also assure the safety of the nation's food supply through inspection of the nation's meat, poultry and egg products. We have a fundamental mission of conserving natural resources and protecting the environment through Forest Service management of 191 million acres of national forests and grasslands and through a variety of technical and financial assistance programs to farms, ranches, and other private lands. And, we protect American agriculture and the public from exotic plant pests and animal disease agents. In doing so, USDA is one of the largest rulemaking agencies in the Federal government, issuing many rules and notices annually that we believe improve human health, protect the environment and make the U.S. a better place to live.

The Department is committed to sound and appropriate risk and cost-benefit analysis. We have used risk assessment widely in natural resource management and plant and animal protection activities. In addition, we are now implementing legislation enacted last fall that created an Office of Risk Assessment and Cost-benefit Analysis which is charged with ensuring that risk analysis is conducted for major rules affecting human health, human safety and the environment. This legislation provides an appropriate balance between prescription and flexibility, which is lacking in H.R. 9.

We believe strongly in risk assessment and that risk assessment generally must be used in analyzing USDA regulations and establishing regulatory priorities. USDA will employ the best obtainable scientific information to assess hazards to human health, safety, and the environment. These assessments will include quantitative and qualitative information. Judgments, assumptions, and default values will be explicitly stated. All appropriate hazards will be reflected in the assessment. When done right, risk and cost-benefit analysis will lead to more cost-effective policy, expedited rulemaking, more timely interventions, an industry more receptive to rulemaking, and greater public support. Such benefits can be lost with inflexible and inappropriate analysis requirements that greatly increase taxpayer costs and hamper our ability to carry out the Department's human health, safety and environmental programs.

A major problem with H.R. 9 is the prescription of formats, approaches, and reviews using methods and language appropriate for toxins and chemical agents. These concepts are inappropriate for the major concerns addressed by USDA programs for human health, safety and the environment, which include food consumption to achieve healthful diets, and

biological agents and environmental consequences of natural resource use, such as soil quality or wildlife populations. The concepts of "exposure," "dose" and "response" do not fit risk assessments of biological agents or many environmental outcomes. For example, pathogens in meat or biological agents introduced through imports are not fixed in quantity. They reproduce and may spread in a matter of hours. Risk changes over time and place as farm products move through the food chain or plant pests move out through the nation. Risk assessment methods must be flexible enough to address these types of hazards and they must allow assessments to be completed expeditiously to prevent a threat from growing into an emergency.

Another major concern of H.R. 9 is its breadth of application. Except as specified in the savings provisions, Title III applies to any positive finding of risk in any final document made available to the public in the context of federal regulatory programs. This opens the door to a massive and costly undertaking of added data collection, analysis, public comment, reviews and possible litigation that in many instances will add no information that improves decision making and prevents timely actions that would solve health, environmental and economic problems. Without adequate qualifiers to narrow the bill's application, the legislation could lead to undesirable results. For example, is such a costly paperwork burden necessary for changing eligibility criteria for contracts voluntarily entered into by farmers who want to restore wetlands?...or restricting access to and use of the national forests during periods of extreme wildfire danger, or making decisions to recall products contaminated with E. coli?

Many regulations function in a dynamic environment which require their periodic and

sometimes immediate modification. The factors determining various entitlement, eligibility, and administrative criteria often change from year to year and regulations must be revised annually to reflect changes in economic and market benchmarks. H.R. 9 would add layers of unnecessarily excessive requirements for such regulations. Under the excessively elaborate procedures of H.R. 9, some USDA risk characterizations could be futile--for example, one done for imported fruit could result in fruit rotting before the H.R. 9 process for risk analysis is even complete.

Examples of USDA risk assessment and rulemaking activities illustrate the problems of H.R. 9.

Control of Plant Pests and Animal Diseases. The USDA oversees the control and eradication of plant pests and animal diseases which could endanger a broad spectrum of the food and agricultural sector as well as human health. For example, the Animal and Plant Health Inspection Service (APHIS) controls Mediterranean fruit fly infestations. A significant national outbreak could result in over \$1 billion dollars in losses to farmers and agribusinesses. To be effective, actions to prevent pest or disease spread must be taken at an early stage and require continual characterization to inform risk management. H.R. 9 could lengthen the risk characterization steps and impede APHIS risk management action to control the 1-2 infestations which occur each year.

A recent example of APHIS success is the control strategy for the Eurasian pine bark beetle, recently introduced in the U.S., that now infests timber in North Central states. To stop the spread based on timber movement, one State developed a set of 25 actions that the timber industry was asked to implement. APHIS conducted a timely risk assessment that

convinced the State that only 2 or 3 measures were sufficient to control human-caused spread of this forest pest. Had H.R. 9 been in force, the timber industry of this State would likely still be operating under the costly regulatory requirements first imposed by the State.

USDA exerts continuing vigilance by developing risk assessments for the import of agricultural commodities to assure that U.S. crops, livestock, the environment and human health are protected from imported pests and diseases.

International Trade. Although the health of the U.S. population is of primary concern in these import activities, it is worthwhile to consider the unintended consequences of H.R. 9 on international trade and agribusiness activity. USDA conducts risk assessments of imported plant and livestock products prior to their entry into the United States to ensure that they are free of exotic pests or disease agents. These risk assessments and characterizations identify the hazard and describe the risks associated with the potential importation as a public notice. Risk management decisions are made on the basis of these assessments. For minor or routine imports, these assessments may take a short time. H.R. 9 would introduce a much lengthier procedure of analysis and comment loops that would deprive the importer of imported product and lead to lost economic activity and jobs.

In turn, procedures that cause the U.S. to limit imports are likely to result in the exporting countries responding in kind and reduce the U.S. ability to export its agricultural commodities. U.S. origin food and food products have a global reputation for safety, wholesomeness and reasonable prices which has boosted U.S. agricultural exports to an expected \$45 billion this year. Occurrences which damage this reputation have the potential for diminishing our export markets.

The General Agreement on Tariffs and Trade and the North American Free Trade Agreement contain specific provisions for risk assessment which are appropriate for the biological agents whose movement they are intended to control. These provisions require that such assessments follow international standards of risk assessment and be performed in a reasonable period of time so as not to impede trade. The application of Title III provisions may result in dual risk assessments being required and could raise complaints that such measures are a disguised trade barrier. H.R. 9, coming at a time when countries around the world are developing their Uruguay Round implementing procedures, offers them an unfortunate example of how to impede imports.

Food Safety. Foodborne pathogens are now recognized as an important cause of human illness and death. Some of these pathogens are primarily associated with meat and poultry. The cost of foodborne illness related to meat and poultry alone is estimated at \$4.5-\$7.5 billion annually. The hazards are well documented and based on studies of patterns of human illness. The technology exists to dramatically reduce contamination levels. The USDA believes that sufficient evidence exists to act and has opened the dialogue needed to significantly reduce this problem by recently proposing the phase-in of Hazard Analysis of Critical Control Point (HACCP) processes. Had H.R. 9 been in effect, added requirements for data, additional analysis such as for substitute risks and comparative risks, peer review, and other features would only serve to delay the reduction in foodborne illnesses.

Natural Resources. USDA's Forest Service manages the national forests as multiple use natural resources. Forest Service timber sales require environmental documentation. Since these documents are public documents, an argument could be made that they fall within

the purview of H.R. 9, requiring a review of the risk characterization and public notice of the original and reviewed risk characterization. In addition, time for public comment, agency response to public comment, and possible judicial review must occur. This process would cause enormous and unnecessary costs and delays for the grazing, mining, recreational, and timber industries and further drive up the costs of natural resource-based commodities and services.

Additionally, another example of the overly broad reach of these provisions is forest fire risk characterizations. These characterizations are daily events in national forests during dry seasons. Again, under a broad reading, regulation of public access to and use of the forests based on these characterizations could fall under the provisions of H.R. 9, which would delay warnings past the time of their usefulness.

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The USDA believes in sound, science-based risk assessment. H.R. 9, however well intentioned, establishes a too prescriptive set of procedures that will add unnecessary cost to the taxpayer and result in deleterious effects on the Department's programs that improve the lives of Americans every day. USDA's recently enacted risk assessment statutory requirements are sufficient to provide flexibility to allow scientists, risk assessors and economists the leeway needed to provide appropriate analysis to assure both effective and efficient use of regulatory resources.

The CHAIRMAN. Thank you, Mr. Collins.

Mr. Schultz.

Mr. SCHULTZ. Thank you, Mr. Chairman, and Members of the committee. I appreciate the opportunity to testify here today on behalf of the Food and Drug Administration.

The FDA is a public health agency, as all of you know, that is responsible for ensuring the safety and, in some cases, efficacy of a wide range of products, including foods, drugs, blood, cosmetics, and medical devices such as CAT scans and heart valves. We regulate or we are responsible for the safety of products that account for 25 cents of every dollar that consumers in this country spend. We do that job with a staff of fewer than 10,000 employees and with a budget of less than a billion dollars.

We agree with the authors of this bill that government decision-making can be improved. And as part of the Vice President's National Performance Review, the Agency is currently engaged in an intensive effort to identify regulations that can be—or requirements that can be eliminated because they impose an unnecessary burden on industry, that can be eliminated because they use unnecessary resources of the Agency, or programs that can be changed so that we can do our job of protecting the public health better with fewer resources.

The Food and Drug Administration also agrees with the authors of the bill that risk assessment is a useful tool. The Agency has been doing formal risk assessments for more than 20 years. In fact, we like to think of ourselves as pioneers in the field. But—and this is the major point I want to make in this testimony—there are times when a full-blown risk assessment is appropriate, and there are times when it is not. And the problem with H.R. 9 is that it doesn't make this distinction. Instead, it adds extensive new procedural requirements to decisions that the FDA must make every day involving enforcement actions, product approvals, and regulations.

And I'd like to spend the remainder of my testimony discussing three examples of how this bill will create a serious impediment to our ability to do our job.

The first example involves blood. The FDA is responsible for the safety of the blood supply. We have detailed regulations telling blood banks how to handle blood. They involve multiple layers of protection. And we do this job in part by having inspectors periodically go into blood banks and make sure that the blood banks are following the procedures that are required. If the inspector finds a problem, then the inspector, along with higher level officials in the Agency, must exercise a judgment as to what action to take.

For example, if the inspector finds that donor records are sloppy and that there is no clear record of whether the bank is accepting blood from a person, from people with HIV infection or hepatitis, then the Agency must make a quick assessment of risk, a risk assessment under this bill, and decide what action to take. Should it shut down the bank? Should it quarantine some of the blood? Should it impose some other restriction? Or is it appropriate to do nothing?

H.R. 9 would mean that the Agency couldn't make that judgment without going through an elaborate process, and it simply couldn't make it in the time that it needs to make it.

This same problem that I've identified for blood occurs in a wide range of enforcement actions that the FDA must take every day, ranging from inspections of drug manufacturing plants and device plants to import of foods and inspection of food and manufacturing plants.

The second example I'd like to talk about involves product approval. And the example I want to use is yellow number 5, which is a color additive that's used in foods and other products. And we recently had a request to allow the use of color additives, of yellow number 5, in certain cosmetics and drugs that are near the eye. And we require the company to do a risk assessment to identify what the risk was and so we could look at it and make an evaluation as to safety.

No one has ever raised any questions about the thoroughness of that risk assessment or about our procedures, and yet under this bill, the FDA and the company, in fact, would have to supply 15 additional pieces of information at a significant cost to the Agency in terms of review, a significant cost to the company, and a significant delay in the time it would take us to make that decision.

And I want to stress that this is in a context where nobody has raised an issue or said we are not doing an adequate job in this area.

This same point is true for other products that we must approve, whether we're talking about drugs or medical devices or even permission to investigate a drug. When a company asks to do a drug investigation, we in essence must make a risk assessment. But we try and do it in a very timely manner, in less than 90 days. And we exercise judgment, which is I think what people want us to do, as opposed to requiring a huge amount of information and delay.

The final example I want to mention has to do with peanuts and peanut butter. The risk of peanuts, if there is one, has to do with a contaminant called aflatoxin that's in the mold, and it gets in the—it gets in the peanuts. And it's a very potent carcinogen. And so we have what are called action levels where we try and keep aflatoxin at the lowest possible levels.

And I don't think anybody doubts that that's the right thing to do and that this is a serious matter. In 1990, the peanut crop in the southeastern United States had aflatoxin at levels significantly higher than where our action levels were, where the requirements were. And the impact, if we had literally applied the prior standards, would have been to require destruction of 25 percent of the peanut crop at a cost of \$1.3 billion.

The Agency didn't do that in 1990. Instead, it spent three weeks doing a risk assessment and came up with a plan where the peanuts could basically be used in animal feed and procedures to make sure they did not get diverted to human use. But we don't believe we could do that under this bill. We don't believe that it would be possible to do the risk assessment in three weeks. In fact, it would take four months.

In conclusion, Mr. Chairman, H.R. 9 would add extensive new procedural requirements to tens of thousands of decisions involving informal assessment of risks that the FDA must make every year. It would severely hamper the agencies ability to protect the public health and safety, and would create additional unnecessary re-

quirements for companies seeking permission to market new products.

I would be happy to answer any questions.

[The prepared statement of Mr. Schultz follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

TESTIMONY BY

WILLIAM SCHULTZ

DEPUTY COMMISSIONER FOR POLICY

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON SCIENCE

HOUSE OF REPRESENTATIVES

FEBRUARY 3, 1995

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman and Members of the Committee:

I am William Schultz, Deputy Commissioner for Policy of the Food and Drug Administration. I appreciate the opportunity to discuss the impact of Title III of H.R. 9, the "Job Creation and Wage Enhancement Act of 1995," which relates to risk assessment, on the programs and activities of the Food and Drug Administration (FDA).

As the Members of the Committee are well aware, the FDA is a public health agency. The main statute that we are charged with implementing, the Federal Food, Drug and Cosmetic Act (FDC Act), is designed to ensure that products ranging from drugs, blood and CAT scans to mushrooms, hair spray and fish, are safe, and in many cases effective. The products that we regulate account for 25 cents of every dollar that consumers in the United States spend. We do this job with fewer than 10,000 employees, and a budget of less than \$1 billion per year. (See Addendum for further description of FDA activities.)

Inevitably there are costs to industry of ensuring that products are safe and effective. This is particularly true for drugs, medical devices and other products that require FDA approval before they can be sold. We are acutely aware that any regulatory requirement that we impose must be justified

on the basis of our basic mission to protect public health and to protect consumers from fraud. As part of the Vice President's recently-announced review of federal Agency programs, we currently are intensively evaluating all our programs, to identify requirements that are unnecessarily burdensome on industry. It is my belief that as part of this effort we will identify requirements that impose significant burdens, whether they be on the regulated industries, or in some cases on the Agency, that can be eliminated.

FDA believes risk assessment is a useful tool. We have been using traditional risk assessment techniques, which have similarities to the risk assessment requirements of H.R. 9, for more than 20 years. We like to think of ourselves as pioneers in the field.

We also believe, however, that there are times when formalized risk assessment procedures are appropriate and times when they are not. As currently drafted, H.R. 9 would add what in most cases would be extensive new procedural and substantive requirements to the tens of thousands of decisions involving informal assessment of risk that the FDA performs annually. It would increase the burdens and costs to industry, and delay products reaching the marketplace, thus resulting in a deleterious impact on public health, consumer protection, and small businesses. H.R. 9 also would cause unacceptable delays in the Agency's enforcement programs. Such delays could cause perishable products to spoil and

other products to age beyond their shelf life before decisions could be made on their safety. It would require additional cost benefit analyses and peer review in situations where, in our opinion, no improvement in the ultimate decision making would result. Because the Agency's compliance with H.R. 9 would be judicially reviewable, the FDA would have to expend considerable resources compiling a record reflecting its compliance with the bill's requirements. FDA also would have to look to industry to compile data, which in many cases would be of questionable value, further increasing burdens on industry.

In other words, Mr. Chairman and Members of the Committee, the additional requirements of the bill would add layers of bureaucracy to the Agency's decision-making process, increasing the cost of Agency regulation, without any benefit to the consuming public or the regulated industry. It also would severely hamper the FDA's ability to protect the public health and safety, as well as creating additional requirements for companies seeking to market new products.

I. H.R. 9 WOULD MAKE IT IMPOSSIBLE FOR THE FDA TO TAKE MANY  
ENFORCEMENT ACTIONS AND IT WOULD DELAY PRODUCT APPROVALS.

FDA assesses risks tens of thousands of times each year. The circumstances calling for an assessment of risk range from review of applications for new human drugs and issuance of regulations to protect

against transmission of infectious disease through the blood supply, to determining whether signs of rodent infestation in a warehouse render the food stored there adulterated. In the case of significant regulations addressing health risks, a scientifically rigorous type of risk assessment is appropriate and already is being done. In the case of a warehouse inspection, a determination fully adequate to meet the requirements of the FDC Act can be made without a risk assessment of the type required by H.R. 9, and the delay that would be required to complete such a risk assessment would impose either unnecessary health risks on the public or substantial and unnecessary economic losses on the regulated industry. In the case of an application for approval of a prescription drug, the Agency conducts an equally rigorous, but somewhat different analysis.

Whenever the FDA decides that a product or manufacturer is violating the FDC Act, whether the violation involves a defective heart valve, cheese with listeria, food that is filthy, or blood that is not being documented properly, it must perform an evaluation of risk, which would be a "risk assessment" within the meaning of H.R. 9. Complying with H.R. 9 would make taking those actions extremely difficult, and would severely impede the Agency's ability to enforce many of the provisions of the FDC Act. This is particularly the case for foods, but also applies to the Agency's compliance activities related to drugs, devices, blood and vaccines.

In fiscal year 1994, the FDA took over 186,000 surveillance actions, of which 29,459 resulted in import detentions, 7,380 resulted in adverse findings, and 3,247 resulted in recalls. The determination as to what course of action is appropriate following an FDA inspection which finds that the law has been violated is, in part, based on an assessment of risk. That risk assessment takes into account a variety of factors such as the nature, scope, and potential impact of the alleged violation.

Superimposition of Title III's risk assessment requirements on each of the Agency's decisions on import detention, recalls, or even whether to issue a letter warning to a company that it is in violation of the FDC Act, would greatly increase the public health risk of exposure to unsafe food, drugs and devices. It would needlessly increase the time and resources required for each individual action to redress a violation.

The cost to industry would be increased as well. At present, once the FDA establishes that a product violates the FDC Act, it typically works with the company to determine an appropriate corrective action. The Act prohibits the introduction into interstate commerce of any adulterated or misbranded food, and then describes what constitutes adulteration and/or misbranding. 21 U.S.C. 331(a), 342, 343 At present, the Agency has the flexibility to apply the statute

in a common-sense, effective manner, concentrating its enforcement actions in the areas of greatest consumer protection interest.

For example, foods contaminated with pesticide above the permissible tolerance are technically adulterated, whether or not that contamination constitutes an unreasonable risk to health. Such adulteration can occur when a food contains a pesticide that has not been approved for use in that food. Under current law, once a violation is established, the government can seize the violative product. At present, however, the Agency is able to perform an informal evaluation of the risk to the public (a "risk assessment" under the bill) and to tailor the enforcement action to the nature of the hazard presented by the violation. Were the requirements of Title III to apply to each such assessment of risk, the Agency would not have the flexibility necessary for such individualized enforcement determinations. In some cases the Agency might not bring the action. In other cases, it might be forced to apply the statute literally (avoiding any necessity to perform an assessment of risk), to the detriment of the industry.

In other situations, such as the approval of a product, the Agency often performs a thorough evaluation of risk, but the procedures prescribed by H.R. 9 are inappropriate. Each year the Agency evaluates thousands of applications to approve human and animal drugs, medical devices, vaccines and food additives. It appears that H.R. 9 could increase the risk assessment burden in

product approvals for these products. This would delay approval times and make it more difficult for industry to get some products to market. H.R. 9's risk assessment procedures seem to apply more specifically to assessments of carcinogens and other toxins. It appears that applying the risk assessment procedures of H.R. 9 to our product approvals may result in the imposing of additional testing requirements on the product's manufacturer, longer reviews by FDA, and delays in getting those products to the market.

## II. H.R. 9 COULD REQUIRE RISK ASSESSMENTS IN SITUATIONS WHERE A FORMAL ASSESSMENT WOULD BE A WASTE OF RESOURCES.

The decision as to how elaborate a risk assessment is appropriate should be made on the basis of what information gained through risk assessment can be expected to contribute to the decision-making process. Often, the risks FDA confronts are already known or well-established (e.g., the risk to human health from toxicants such as listeria in manufacturing plants, or excess doses of elemental iron). In such cases, a formal risk assessment is unnecessary. In other circumstances, as when a product offered for import appears to violate the FDC Act, so little is known about the product that a formal risk assessment can not be done. For example, recently, when the FDA detained medical devices made in Pakistan, it did so because they were not stainless steel as labeled. Because FDA

could not ascertain what materials were used to manufacture the devices, it had no basis for a detailed assessment of the risks of the product.

The imposition of "one-size-fits-all" requirements on the enormous range of decisions affecting health and safety made by the FDA would result only in great inefficiency and ineffective government. This type of statutory requirement ignores the different statutory mandates under which the FDA and other executive branch decisions are being made, and whether those mandates are absolute, as typically is the case with the FDC Act. It deprives Agency management of the ability to make critical decisions regarding allocation of resources to particular problems or categories of problems.

### III. TITLE III'S EXPANDED REQUIREMENTS FOR COST-BENEFIT ANALYSIS AND PEER REVIEW ARE BURDENSOME AND UNNECESSARY.

The FDA also has serious concerns regarding the requirements for additional cost-benefit analyses and peer review of risk assessments set forth in Subtitles B and C of title III. Title III-C would require peer review of certain risk assessments and cost/benefit analyses, although the language is so confused that the scope of the requirement is unclear. We believe peer review would be required for risk assessments and cost/benefit analyses in connection with a rule having an

impact of \$100 million; the requirement may also be intended to apply to any cost/benefit analysis of a rule with an impact of \$25 million or more.

Since 1981, the FDA has been preparing cost benefit analyses for rules that have an annual effect on the economy of more than \$100 million. Since subtitle B changes the definition of what is a "major rule" for purposes of cost benefit analysis from \$100 million to \$25 million, we believe cost-benefit analyses would be required for a far larger number of regulations than currently is the case.

These requirements would be applied even where cost impact is not a factor that may be considered under the statutory mandate. For example, under the FDC Act, the FDA must go through rulemaking when approval is sought for a food additive; the approvability of the product depends on a determination that the product is safe, without regard to costs and benefits. Yet under H.R. 9, a cost-benefit analysis would have to be performed if the impact on the economy is \$25 million or more. Moreover, the data for that analysis would have to be provided by the applicant at significant additional expense and delay.

Under H.R. 9, cost/benefit analyses would be required for a far larger number of regulations. FDA estimates that a significant number of its rules, including regulations to assure the safety of fish and other seafood products, to protect children from accidental poisoning by iron supplements, and to establish standards

for mammography clinics would exceed the \$25 million threshold, compared to an average of four a year under current rules. Analyses accompanying some rules also would be subject to peer review. These requirements would be applied even where, as is the case with the food and drug laws, cost impact is not a factor that may even be considered under the statutory mandate to protect the public from adulterated and misbranded products.

There is no general agreement on the appropriate technique for estimating economic impact equivalent to the consensus on the scientific methods to be used to assess impacts on human health. In addition, the likelihood is that adequate data will be unavailable. As a result, we would expect the economic peer review process to produce many disagreements with Agency conclusions leading to further discussions and delay.

\* \* \*

I would like to close by returning to my opening proposition, which is that Title III could have a devastating impact on the Agency's ability to enforce the laws within its jurisdiction. Given the extent to which the FDA and other federal agencies already use the tools of risk assessment and cost benefit analysis to inform their decision-making, the effect of Title III will be to undercut seriously our ability to implement the laws that we are charged with enforcing. Although Title III would leave in place these statutory requirements, many of the other provisions of H.R. 9 would vastly increase the

difficulty of enforcing the law. It would mean more government and less public health protection. The end result would be far less effective government because of burdensome and unnecessary bureaucratic requirements that will compromise the government's ability to protect the health and safety of all Americans.

I would be happy to answer any questions.

## ADDENDUM

## BACKGROUND INFORMATION ON FDA ACTIVITIES

It is important to provide some detailed background information to the Committee on the scope of FDA's activities in carrying out its public health mission. An understanding of the regulatory function of the different programs that would be affected by the Title III risk assessment provisions of H.R. 9 is crucial in determining their impact.

## FDA'S PUBLIC HEALTH MISSION

The FDA is responsible for regulating products worth about \$1 trillion -- the equivalent of about 25 cents out of every dollar spent by American consumers. FDA's mission, defined in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, is to ensure that:

- o Foods are safe, wholesome, and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe;
- o Regulated products are honestly, accurately and informatively labeled; and,
- o Noncompliance with legal requirements is identified and corrected; and unsafe or unlawful products are removed from the marketplace.

Each of the FDA regulated product areas is diverse, with its own set of scientific issues. For example, medical devices range from bandages to artificial hearts. Radiation-emitting products run from microwave ovens to the ultra-high-tech magnetic resonance imaging machines that permit doctors to diagnose disease with far more precision than ever before. Foods range from a loaf of bread to a genetically engineered tomato. Our challenge is to keep protecting the public health, to be on the cutting edge of science so that we may continue to approve innovative products, and to regulate the various industries responsibly and effectively.

The United States has the safest food supply in the world, yet we constantly have to protect consumers from foods containing botulism, listeria, and other contaminants. We have the most innovative pharmaceutical industry, and the finest pharmaceutical products, yet every year, we have to make difficult decisions

concerning product approvals and poor manufacturing practices. Our medical device industry is vigorous, producing outstanding products, yet as the current problem with Telelectronic's pacemaker shows, serious problems can still occur. Our emerging biotechnology industry will play a significant role in maintaining our economic leadership into the next century, yet it has found that all new discoveries do not result in useful products. The industries FDA regulates are very strong industries with excellent records of sales both here and abroad. These accomplishments are due in part to the high standards set by U. S. businesses based on the regulatory framework established by the Congress and administered by the FDA.

#### FOOD SAFETY

The food-related provisions of the Federal Food, Drug, and Cosmetic Act (FDC Act) are designed to ensure that food in the marketplace is safe and wholesome, and truthfully and accurately labeled. The law places on food manufacturers, producers, and distributors the burden of ensuring that food is not potentially harmful or unfit, using drugs for food-producing animals safely and appropriately, and using registered pesticides according to label directions so that illegal residues do not occur. The FDA's job is to regulate and prevent illegal, unacceptable and unsafe chemical residues and contaminants in the Nation's food supply. We carry out these responsibilities by inspecting firms, sampling and analyzing products to determine if the producers of these goods have complied with the provisions of the FDC Act, and taking appropriate enforcement actions when the Agency finds that the firms are not complying with the law. We constantly strive to improve our existing monitoring programs and enforcement efforts.

Through FDA's premarket approval activities for new animal drugs and for food and feed additives, and through informal and formal enforcement actions, the Agency minimizes the unsafe and illegal chemical residues and contaminants in the food supply. Some residues, however, may be unavoidable due to environmental contamination or other human activities. In these instances, FDA's job is to determine the levels of a particular contaminant that may pose a health hazard to various segments of the population and take all necessary steps to protect consumers from exposure to these contaminants.

Although the Nation's food supply is safe, unfortunately food-borne illnesses from pathogenic microorganisms are not

eliminated. Absolute safety cannot be achieved. Within the Public Health Service, FDA works with the Centers for Disease Control and Prevention (CDC) to assess food safety through risk assessment and risk reduction. FDA and CDC also work with the United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) to develop and carry out regulatory and surveillance programs, cooperative programs with the states, and educational activities.

State and local food regulators provide oversight of the vast retail segment of the food industry -- the million plus restaurants, grocery, and convenience stores, vending operations and institutional food providers. These State and local agencies are an integral part of the overall food safety "umbrella."

#### PRODUCT APPROVAL PROCESS

Under the FDC Act, new drugs and new medical devices must be shown to be safe and effective before they can be marketed. Similar standards are applied to biologics under the PHS Act.

Although the product approval process varies in some particulars depending on whether the product is a drug, device or biological, the basic scheme is the same. A new drug, device or biological may not be distributed in interstate commerce (except for clinical study) until a sponsor, usually the manufacturer, has submitted, and FDA has approved, an application for pre-market approval. This application must contain scientific evidence that demonstrates that the product is both safe and effective for its intended uses.

For a drug, device or biological that has never been used before, the premarket application typically includes the results of animal and clinical testing. To use the drug example, the first step a sponsor must take is to test the drug in animals for toxicity. The sponsor submits that animal testing data, along with additional information such as the drug's composition, manufacturing, and control data, and develops a plan for testing the drug in humans. The sponsor submits these data, along with details regarding its study plan, to the FDA in the form of an Investigational New Drug (IND) application. FDA reviews the IND to assess whether the animal tests establish that human subjects are not likely to be exposed to unreasonable risk of harm.

At that point, the first safety studies of the drug can take place in humans -- usually healthy volunteers. Once safety

studies are completed, the drug is studied for its effectiveness--first in small studies, then in larger studies. These studies can examine additional uses, obtain further safety data including long-term experience, and consider additional population subsets, dose response, etc. FDA strongly encourages sponsors to work closely with the Agency in planning definitive clinical trials so as to ensure adequacy of clinical trial design.

Once the testing is completed, the sponsor submits the test results to FDA in the form of a New Drug Application (NDA). FDA's medical officers, chemists, statisticians, and pharmacologists review the application to determine if the sponsor's data in fact show that the drug is both safe and effective. Frequently, FDA will use one of several standing external-expert advisory committees to review the data and obtain expert opinion and advice on product safety and effectiveness. The manufacturing facility is evaluated to ensure that the product can be produced to meet quality and purity standards. Safety and effectiveness data may also be audited by FDA through on-site inspections to verify that complete and truthful information has been provided in the application.

#### DEVICE PRE-MARKET NOTIFICATION

The Medical Device Amendments of 1976 created two pathways a manufacturer could follow to market a medical device: (1) premarket notification, known as a "510(k)"; and (2) premarket approval application (which is comparable to an NDA). Almost all devices marketed subsequent to the 1976 amendments require clearance or approval through one of these two mechanisms.

Under the 510(k) process, FDA must determine whether a device is "substantially equivalent" to a legally marketed device. A company must submit an application with information that will enable the Agency to make that determination. If the new device is found to be substantially equivalent to a legally marketed device, the company can then market the product.

#### REGULATION OF BLOOD PRODUCTS

FDA monitors and regulates the companies that collect, process, and transfuse blood. Our goal is to ensure that this Nation's blood supply is as safe as possible. The introduction of screening tests for hepatitis, HIV, and other infectious diseases has significantly increased the safety of blood over the past

couple of decades. But the use of these tests, the use of new technologies, and an increase in the number of blood products being produced, have also made blood banking far more complex than ever before.

Blood banking must conform to quality control requirements comparable to those of pharmaceutical companies producing life-saving products. Like any medical product industry, blood banks are responsible for ensuring the safety of their products and for complying with the rigorous standards that are necessary to protect our blood supply. We are committed to holding blood banks to those standards.

FDA carefully monitors the recordkeeping and other essential elements of safe blood preparation, such as donor screening and testing, blood labeling, storage, and handling. Each year, the Agency inspects all blood establishments and examines significant aspects of their performance. If FDA finds any problems or deficiencies, we require the firm to take prompt corrective action. The Agency checks to make sure that these difficulties are fully and quickly resolved.

If the blood establishment does not take corrective action, or if FDA finds dangerous violations, FDA can suspend or revoke the firm's license, seize its products, and take other legal actions that can result in civil or criminal penalties against the blood establishment and its officials.

#### FDA'S IMPORT PROGRAM

FDA is responsible for reviewing imports as part of its public health mission. Under the FDC Act, the legal requirements are the same for imported and domestic products. The approaches used to ensure conformity with these requirements, however, are necessarily somewhat different. For example, the law takes into account that FDA does not generally inspect foreign food producers by specifying that food imports may be detained (i.e., prohibited from distribution in domestic commerce) and refused entry if the food "appears" to be in violation of the FDC Act. [See 21 U.S.C. §381(a).]

Imported products are subject to inspection by U. S. Customs. Customs notifies FDA of shipments of FDA-regulated products, and FDA decides whether to sample the product and test it or to take other appropriate action to determine if it meets U.S. laws. Shipments that do not comply with our statutes may be detained

until they are brought into compliance. If the goods cannot be brought into compliance, they must be re-exported or destroyed.

In addition to refusing entry of an individual shipment of a violative import, FDA may invoke a process known as "automatic detention" when the Agency believes that a particular violation may be repeated. Under this control measure, all subsequent shipments of the same suspect product are automatically detained --and thus not distributed in domestic commerce--until the importer, shipper, producer, or a responsible agency of the exporting country provides sufficient evidence that the shipment complies with applicable U.S. law.

#### SUMMARY

As you can see, FDA has an enormous impact on American industry through the public health laws that we implement. We are fully aware of that impact, and we are intensively evaluating all our programs to identify ways that we can reduce unnecessary burdens, while maintaining the high level of consumer protection on which American consumers have come to rely.

The CHAIRMAN. Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman. Mr. Chairman, as you know, I have asked for comments on this legislation from other agencies, and I ask unanimous consent to enter into the record submissions received in connection with my request from EPA, Nuclear Regulatory Commission, TVA, Department of Health and Human Services, Agriculture, National Transportation Safety Board, Treasury, Veterans Affairs, and FEMA.

Do we have unanimous consent to do that?

The CHAIRMAN. Without objection.

[The information follows:]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JAN 31 1995

THE ADMINISTRATOR

Honorable George Brown  
Ranking Democratic Member  
Committee on Science  
U.S. House of Representative  
Washington, D.C. 20515

Dear Congressman Brown,

I am pleased to respond to your questions regarding HR 9, the Job Creation and Wage Enhancement Act. This Act is of great significance to us and to other Federal Agencies, and has the potential to drastically alter how we protect our health and our environment. The provisions relating to the evaluation of risk and its role in regulatory decisions are particularly important.

As you are aware, risk assessment is an important tool that we have been using at the Environmental Protection Agency for more than twenty years. We use this tool in a variety of ways, to help us make decisions about National regulations such as ensuring that drinking water is safe for everyone in this country to drink, to help us set priorities among many different risks clamoring for attention and action, to help us differentiate big problems from small problems, and to make decisions about specific sites or geographic areas.

The EPA uses risk assessment to make certain that our children are protected from unsafe chemicals and pesticides, ensure that families that live around Superfund sites are not harmed, make decisions about permits such as for waste incinerators, set priorities, and make decisions about enforcement actions. In sum, risk assessment is a tool that we use in all EPA programs in many, many ways.

Because risk assessment is so important to our work, we have continuously invested the resources to improve this fledgling science, and to provide the tools and the guidance that would assist both risk assessors and decision makers in optimal application of this tool. So, for example, over the years we have published a number of guidance documents on carcinogenicity, mutagenicity, developmental effects, chemical mixtures, and exposure assessment, and are currently preparing guidelines on reproductive toxicity, neurotoxicity, and ecological risk assessment. This compendium of guidance is unique in the world in its scope, and was designed to make the process of risk assessment as understandable, consistent and transparent as possible to scientists, policy makers and the public.

We are very much aware of the fact that risk assessment is an evolving science -- whose continued evolution we must continue to encourage. This means that for now and into the future, there will be a need to constantly improve this tool. We must recognize, however, that the many

different applications of risk assessment require carefully tailored improvements -- there is no "one-size-fits-all" solution to the problem.

When I testified before the House Science Committee earlier this month, I set out a number of principles that needed to be met, in order for us to be able to support risk assessment legislation. At that time I said that "the Administration would support risk assessment legislation that allows fair, effective and affordable use of this tool". I also pointed out at that time that there were parts of the original Contract with America that caused us concern because it might freeze science in time, open scientific analyses to judicial review, result in inappropriate delay, and cause endless loops of analysis and review.

HR 9 is a modification of the original language in the Contract with America, and in fact, there have been some changes made, in some areas. This Bill is still fraught with problems, however, especially when Title III is read together with other Titles that also impact the assessment and decision-making process. Specifically:

**1. HR 9 contains extensive procedural requirements for analysis, that will increase costs to industry, government and the consumer, and result in serious delays in protection of health and the environment.**

There are many different reasons why EPA does risk assessments, and the scope of the assessment is currently gauged to the type and significance of the decision. Some assessments are very brief and are completed in a day or two, while others (e.g., the recent reassessment of dioxin) may take several years to complete. By prescribing what assessments and reviews must contain, and by prescribing how they must be implemented procedurally, many of our current very quick assessments will become unduly complex, cumbersome and costly. The recent report of the National Academy of Sciences, "Science and Judgement in Risk Assessment," stated that "...the committee believes that EPA should undertake an iterative approach to risk assessment. An iterative approach would start with relatively inexpensive screening techniques... and then for chemicals suspected of exceeding de minimis risk move on to more resource intensive levels..." In many cases, HR 9 would require resource intensive assessments at a much earlier stage in the rulemaking process.

To provide the information called for by this Act, industry would also face significantly increased costs. Whether for the 5 - 10% of the Premanufacture Notifications where there is a positive finding of risk, or the registration of safer pesticides, the requirements of this Bill will impose significant costs in time, data collection and analysis.

The Act will also directly cost the public more. For example, actions to reduce the regulatory requirements for disposal of PCBs, or to redesignate ozone non-attainment areas, or to ease the burden on industries that emit hazardous air pollutants, all actions designed to lower costs for industry and the consumer, would all be made more complex and time consuming, resulting in continued, unnecessary, higher costs to the consumer.

HR 9 would make it more difficult to remove unsafe chemicals from the market, more difficult

to introduce safer alternatives, and would stifle industrial innovation. The bill calls for much more extensive risk assessments, cost benefit analyses and regulatory impact analyses before the EPA can take action. In addition, industry that wants to put newer and safer chemicals on the market will likewise have to conduct more studies and analyses before these new chemicals can be approved. The result will be gridlock of the review system, a decrease in our ability to deal with unsafe chemicals currently on the market, and a significant delay in the introduction of new chemicals to the market. For example:

- New chemicals and new pesticides require approval by EPA before being marketed. Several thousand such actions are taken annually by the EPA, and most chemicals pass through the screening process without restriction. However, under HR 9, if the results of the screening process were to indicate that a chemical may be too hazardous for unrestricted manufacture (which occurs for an estimated 5 - 10 % of the PMNs submitted annually), EPA would have to support that determination with a much more extensive risk assessment -- in place of today's expedited decision process that relies on limited data and scientific judgement. What is now accomplished in less than 90 days could become a protracted data gathering and analysis effort. The introduction of new, and possibly safer chemicals, and pesticides could be significantly delayed.

## **2. The strict application of cost- benefit and cost-effectiveness criteria may exclude important health and environmental effects from consideration, and potentially conflicts with other important decision factors.**

There are many decisions about environmental protection that either are not amenable to cost effectiveness and cost benefit consideration, or for which the information for such an analysis is not available. Often, such information is not available because our understanding of the science is insufficient to permit quantification of critical health and ecological effects. In either case, important health and environmental considerations fall by the wayside. We are concerned that health and environmental effects that science is unable to quantify today will not be taken into account in such decisions. For example, developmental effects in children, reproductive effects in men and women, neurotoxic effects, and ecological effects of many types cannot be fitted neatly into these equations. To ignore such effects would be inappropriate, yet HR 9 would lead us down that road.

### **•Many existing statutes require other decision criteria**

HR 9 could be read as amending a tremendous range of carefully developed environmental statutory provisions. Many current statutes do not permit cost effectiveness or cost benefit to be the criteria by which a decision is made. For example, national ambient air quality standards must be protective of human health with an ample margin of safety, and may not take costs into account. Whether or not HR 9 is meant to revise standards for action established in other laws needs to be clarified, and these fundamental decisions should be addressed in the appropriate context.

- **EPA currently takes into account distribution of costs and benefits, technical**

**feasibility and other key factors; under HR 9, parts of our population, such as Native-Americans, Asian-Americans or African Americans, pregnant women and children may be excluded from consideration.**

Several parts of this Act when read together give rise to this concern. One part of Title III discusses and defines "best estimates" of risk in a vague and unclear manner, but seems to indicate a preference for estimates of central tendency and average exposures. The legislative history of this section may be such that a court that reviews a risk assessment in the future may decide that averages are what is required. Groups outside this average, such as the groups above, may have unique exposures because of their proximity to contaminated sites, their dependence on contaminated fish as a major source of protein, etc., and may therefore be excluded from consideration. Similarly, the cost-effectiveness and cost benefit criteria discussed above would compare "most plausible", or average costs and benefits, and this may also result in such highly exposed groups being excluded from decisions to protect the health of people in this country.

HR 9 requires the Agency to develop information on efficiency: the costs and benefits to society as a whole --- but ignores who bears the burden. The result could be the allocation of risk to the less powerful minority groups, as long as benefits to society as a whole outweighed the costs

**3. HR 9 sets up a detailed and inflexible process for regulatory decision-making that is counter to EPA's commitment to a common-sense approach -- an approach that uses flexibility, creativity and innovation in reaching environmental goals.**

HR 9 has a single prescriptive formula for what must be included in a risk assessment and a risk characterization, describes precisely how a peer review must be done, and has a long list of items that must be included in a Regulatory Impact Analysis. In many cases, such analyses do not add value to a decision, and will result in more inefficient and costly governmental actions. In addition, these prescriptive requirements will result in delay and the wasteful expenditure of private sector resources -- all because HR 9 tries to define precisely what must be done on every occasion

- EPA, has over the years, developed many different types of risk assessments and peer reviews that are tailored to the type of decision that is being made. Risk assessments, cost effectiveness and cost benefit analysis, peer review and regulatory impact analyses are all important tools that must be used appropriately. Specifying a hatchet when a scalpel is called for, and vice versa is often wasteful and may frequently result in perverse outcomes. These types of decisions cannot be easily legislated --- they are more amenable to case-by-case decisions by an Administrative agency.

**4. Risk assessment is a young and evolving science, and HR 9 freezes risk assessment in today's science.**

HR 9 is written about carcinogens and their effects on people. The specifications and prescriptions in the Bill are often not applicable to other health effects, and generally mean little when

considering ecological effects. Yet by listing in a statute items to be included in a risk assessment, the science becomes frozen in time. Under HR 9, as the science of risk assessment evolves and changes, risk assessments would still have to be done the way they were described in the Act in 1995. Archaic and anachronistic science will hinder rational risk reduction.

Many sections of HR 9 are detailed and prescriptive; others are broad and vague, e.g., "most unbiased and most plausible estimate." HR 9 may also open many new doors for judicial review, including review of risk assessments (see section 6. below). Court challenges to the science in the risk assessments would result in decisions that further define what scientific components and analyses the Act means to include. Such judicial decisions will serve to further freeze the science.

##### **5. HR 9 may create new openings for judicial review of risk assessments and other science issues --**

- . . . leading to adversarial legal proceedings that could polarize scientific arguments rather than build consensus in the scientific community, and
- . . . resulting in court decisions that would establish long-standing precedents resistant to change even in the face of new scientific evidence.

The Act has the potential to vastly expand the substantive areas and the procedures arguably subject to traditional Administrative Procedure Act review, through the implementation of many new requirements. Currently, a risk assessment is judicially reviewable in the context of any final Agency regulation or other action that relies on the assessment. It is not clear whether HR 9 is intended to expand the scope of judicial review, but the Bill arguably could make the guidelines for performing risk assessments, and perhaps even the assessments themselves, subjects for judicial review independent of any review of a related regulation or other final Agency action. This could lead to additional judicial challenges at an earlier stage of the regulatory process (in addition to the unaffected right to challenge a final action at the end of the regulatory process). Challenges involving any particular provision for performing risk assessments, such as the peer review procedures or the methodology for determining "best estimates" of risk, could affect many assessments and related regulatory actions. These assessments and related actions might be delayed to await the outcome of litigation, or might have to be redone as the result of such litigation.

In addition to expanding the nature of judicial review, HR 9 could establish courts as the arbiters of cutting edge scientific issues. The prescriptive nature of HR 9 invites judicial review of the details of the components for performing risk assessments. If the guidelines or assessments themselves are directly reviewable, courts will be asked even further to resolve complex scientific issues. The judicial process may not be the best forum for resolving these issues in the first instance. Moreover, the nature of judicial precedents could hamper the Agency's willingness or ability to adopt new improvements in science in its risk assessment activities. If a court is called upon to resolve a scientific controversy concerning any component of a risk assessment, the court's decision will make it difficult to refine the component in the future. For example, if a court is forced to choose among competing methodologies for performing a certain aspect of a risk assessment, it may be very difficult for the

Agency to avoid following the court's selected methodology in the future, even if the scientific community moves towards reliance on a different methodology. This could have the effect of "freezing" the science of risk assessments rather than encouraging (or allowing) further improvements and refinements of the process.

Finally, the requirement for a statement of clear legal authority --- incorporated through Title VII's codification of Executive Order 12291 --- could be interpreted as impacting long-standing precedents involving the authority of agencies to interpret statutes and could invite litigation on this subject.

**6. EPA will be prevented from taking action to reduce known risks -- where action is clearly in the public's interest, but scientific knowledge is inadequate to meet the extensive analyses required by HR 9.**

HR 9 does not explicitly call for quantification of all risks and benefits, yet a broad reading of a number of sections in Title III and Title VII together, leads to the conclusion that this is what is required by the Act. Section 3201 requires certification that the action to be taken is the most cost effective, Section 7004 requires benefits to outweigh the costs, Section 3001 talks about using risk to set priorities; all are based implicitly on an ability to quantify benefits. When read in combination, it seems clear that quantification is necessary. Unfortunately, the state of science today does not permit quantification of many health and environmental effects. So, for example:

- In Milwaukee, *Cryptosporidium* in drinking water caused considerable illness and even death. In 1993, in Washington D.C. and its suburbs, thousands of citizens boiled water for several days because of concerns about *Cryptosporidium* and other microbes.

We are beginning to understand more about *Cryptosporidium* -- for example, we know that people with compromised immune systems, such as cancer patients receiving chemotherapy, are particularly at risk from *Cryptosporidium* and other microorganisms. We do not understand how to accurately measure *Cryptosporidium* in water; we do not know the minimum number of *Cryptosporidium* per gallon that are dangerous to human health. We currently do not know enough quantitatively about its health effects to meet the risk assessment, cost-benefit, and regulatory analysis requirements of HR 9.

If the interpretation of HR 9 is correct that we would be required to quantify these effects before regulating, we would have to wait to take action until we had gathered enough data and done enough research -- while people remained at risk --- or face extensive challenges to the basis of EPA's actions.

It is important to note that the regulated community supports taking steps to deal with this issue in spite of the many unresolved uncertainties that remain.

- EPA banned the use of the chemical pesticide Dinoseb because it caused birth defects, as well as sterility in men. Under HR 9, EPA most likely could not have taken action to ban Dinoseb, because of our inability to quantify the number of men or babies who would be affected at any

exposure level.

- Recent regulations have restricted the use of ethylene oxide in sterilizers. Of particular concern in this decision are women of childbearing age (e.g., nurses) who may work in the vicinity of sterilizers in hospitals, and who may be exposed to levels of ethylene oxide that are dangerous to their unborn babies. Because science is not advanced enough to permit us to quantify the number of babies that would be born with birth defects as the result of such exposures, we might not have been able to take action under HR 9.

### Summary

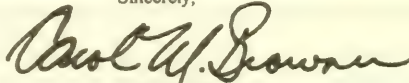
We currently use risk assessment very broadly in the EPA. We are committed to its use, and have devoted significant resources towards its improvement. We recognize that risk assessment is a science that continues to evolve, and that we must do all that we can to support this evolution. As risk assessment continues to evolve, we will focus our efforts on ensuring clarity, comparability, consistency and the highest level of impartial professional judgement.

The policy that EPA established for peer review this year will, we believe, result in a significant improvement in the quality of science at the Agency. This policy is being actively implemented in all parts of the Agency.

For some time now, EPA has been working to update its policy on risk characterization, which I plan to publish shortly. This policy will describe what is meant by risk characterization, and the steps we will take to ensure that risk characterizations are consistent, describe assumptions and uncertainties, etc.

The remainder of this letter provides specific answers to the questions that you have asked. Many of the estimates in these responses were developed with very little time, and so are subject to the usual problems of rushing. I hope that these answers serve your needs and provide the information that you had requested.

Sincerely,



Carol M. Browner

**Questions and Answers**  
**Congressman Brown**  
**January 26, 1995**

- 1. Please identify the programs in the Agency which would be subject to the requirements of the Risk Assessment and Communication Act of 1995 (Title III of H.R. 9), taking into account Title VII and other relevant sections of H.R. 9.**

EPA believes that most of our current programs would fall under the provisions of Title III -- from air and water pollution control programs, to pesticide and toxic chemical regulation programs, to cleanup of hazardous waste.

EPA has long been an advocate of using risk assessment to help make appropriate and effective decisions. We have pioneered the use of risk assessment, and have worked to incorporate the concept of risk into most of what the Agency does. However, we do not always have adequate information or time to conduct a detailed risk assessment, such as that mandated by Title III, for each rule. The level of analysis is frequently tailored to the decision we need to make. In many cases, the specific decision does not require a detailed assessment of risks and costs.

In many programs and for all major regulations, EPA already carries out extensive risk and cost analyses. Thus, H.R. 9 will not necessarily add value to our efforts; instead, it may lead to additional bureaucratic burdens, increased costs, and delays for both EPA and industry. In other programs, EPA will have to conduct risk and cost analyses for rules that do not warrant such extensive and expensive analyses.

As an example, very few current rules developed under the Clean Air Act require separate findings about risk, since most of them merely implement risk management decisions already made by the Congress. The few rules requiring individual risk analyses include those that set new or revised health-based standards for air quality, and those that protect the stratospheric ozone layer. The additional effort required by Title III would be redundant, revisiting risk and cost/benefit issues already settled in the Clean Air Act.

Specific programs that would require a risk assessment using the principles described in Title III include:

- **Air programs:**

- The **National Ambient Air Quality Standards (NAAQS)** program, which sets health-based standards for the nation's air and guidance on achieving these standards.
- The **mobile sources** program, which reduces air pollution from automobiles and other moving sources of pollution.
- The **air toxics** program, which reduces emissions of toxic pollutants into the air.
- The **stratospheric ozone protection** program, which reduces emissions of chemicals that destroy the earth's ozone layer.
- The **radiation standards** program, which sets safety standards for nuclear waste disposal and other potential sources of danger from nuclear radiation.

- **Regulation of chemicals:** There are currently about 60-70 thousand existing chemicals on the Toxic Substances Control Act (TSCA) inventory. EPA is working to target the few that may pose an unacceptable risk to health and environment. Specific programs affected:

- The **Toxic Release Inventory (TRI)** program, which collects toxic release information from manufacturing firms for over 600 chemicals, and makes that information available to the public under the Community Right-to-Know Act.
- The **PCB program**, which sets standards for the management and disposal of PCBs, with the goal of reducing human exposure and environmental impact. Current efforts that are specifically designed to reduce the burden on the private sector -- such as the recent amendments to the PCB disposal rules (**\$3-4 billion savings**)-- could be impacted by the increased requirements.
- The **Lead program**, which is pursuing requirements established under the Lead Hazard Reduction Act of 1992 (Title X) to prevent serious health risks to children who are now being exposed to lead. At the present time there are almost 2 million children under the age of six whose blood-lead levels exceed the threshold for concern established by the Centers for Disease Control.
- **Pollution prevention** programs.

- **Registration/Re-registration of Pesticides:** Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), all pesticide products must obtain a registration before they may be sold or distributed in commerce. EPA must also reexamine its registration

decisions on pesticides initially registered prior to 1984.

- **Hazardous waste programs:**

- The **clean-up under Superfund and RCRA** of sites with contamination by hazardous wastes, and **listing and delisting of hazardous waste** under Subtitle C of RCRA.
- The establishment of **land disposal restrictions** under Subtitle C of RCRA and regulation of the **combustion of hazardous waste** in incinerators, boilers, and industrial furnaces.
- **Chemical accident prevention** under the Clean Air Act, Section 112(r)(7), which requires risk management planning to avoid catastrophic accidents.

- **Water and drinking water programs:**

- **Effluent guidelines** for discharge of pollutants to surface waters.
- **Drinking Water Standards**, for protecting our nation's drinking water supplies.
- **Wetlands protection** programs.

2. Using the definitions of "risk assessment" and "risk characterizations" set out in section 3107 of the Act, how many risk assessments and risk characterizations were prepared by, or on behalf of, the programs in the Agency over the last fiscal year. Of those, how many would be considered a "screening analysis" exempted under Section 3103(b)(2)?

The Agency performs numerous risk assessments and risk characterizations that could fall under the definitions of those analyses in Title III. EPA attempts to carefully husband its analytic resources by developing information appropriate for decision making. The Agency does not follow a "one-size-fits-all" approach. It is important to recognize the considerable differences in the relative amount of effort required to perform major risk assessments as compared with screening analyses. At present, the Agency estimates that it spends about 2 person-days to perform a typical risk assessment for a screening analysis. In comparison, the Agency now spends about just over 12 person-months to produce the typical risk assessment associated with a major rule (approximately 450 FTEs Agency-wide). This figure could increase by an additional 6 person-months (approximate addition of 315 FTEs Agency-wide) to meet the additional requirements described under H.R. 9's provisions.

The following table is an attempt to show the classification of types of risk assessments conducted by the Agency for a given year, in contrast to the classification that would result from implementing Titles III and VII in H.R. 9.

More actions could become subjected to the risk assessment provisions under Title III, as a consequence of meeting the new definition for major introduced in Title VII. Some screening analyses could become major actions, and all minor analyses could become major analyses. In addition, approximately 212 new analyses could be required under Title III, Section 3106, which calls for the Agency to review previously conducted risk assessments.

	<b><u>Total Current Actions Using Current Definitions (EO 12866)</u></b>	<b><u>Total Major Actions Using H.R. 9, Title VII Definition</u></b>
Major Analyses	38	2631
Non-major Analyses	413	0
Screening Analyses	<u>6299</u>	<u>4524</u>
Totals	6750	7155

Note, that due to annual variability in number of activities subjected to screening analysis, the above numbers are intended to provide a characterization of the expected number of actions taken over the course of FY95. Actual totals may differ slightly, primarily due to the uncertainty in the number of actual submitted chemical and pesticide screening assessments. The above figures also do not include risk assessments that may be associated with review and granting of permits, or enforcement related activities for which risk assessments may be performed.

**3. Please describe the Agency's present practices, including references to any published guidelines or procedures, relating to risk assessment, risk characterization, cost-benefit analysis, or peer review.**

**Current Risk Assessment and Risk Characterization Practices**

Risk assessment is the process used to characterize and quantify the potential adverse human health effects and ecological effects of environmental contamination. In risk assessment, information about the toxicity of a contaminant is combined with information on human exposure (or ecological exposure) to that contaminant to produce an estimate of risk.

Risk assessment and risk management provide a framework for setting regulatory priorities and for making decisions that cut across different environmental program areas. This kind of framework has become increasingly important to EPA in recent years. Analyses of risk or its components are an essential and everyday part of the business of the EPA, as are cost and technology analyses.

The President, in Executive Order 12866, has broadly incorporated risk assessment into Executive Branch decision making, consistent with existing law. This order directs that "[i]n setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction." The order also requires each agency to base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for and consequences of the intended regulation. Considerations such as flexibility, government cost of enforcement and compliance, and distributive impacts and equity are to be included.

The basis for EPA's risk assessment practice is the National Academy of Sciences (NAS) paradigm, developed as a consistent method for assessing risk across the federal government. The NAS paradigm defines four elements of risk assessment: (1) hazard assessment; (2) dose-response assessment; (3) exposure assessment; and (4) risk characterization. Risk characterization is the presentation of scientific findings and their strengths and weaknesses so that decision makers can understand and use the information effectively, along with other analyses supporting their decisions. The details of EPA's risk assessment procedures are set forth in EPA's Risk Assessment Guidelines, originally published in the Federal Register in 1986, and continuously updated. EPA's risk assessment guidelines promote consistency across EPA risk assessments by using common approaches to risk assessment and inform the public and the regulated community about the process by which EPA evaluates scientific information. The guidelines are designed to be flexible to encourage the use of all relevant data and the appropriate scientific methods and judgments. EPA is committed to using the best available science for risk assessment. EPA's guidelines are also harmonized with international efforts aimed at similar goals.

In 1992, EPA adopted an agency-wide policy for risk characterization. The policy promoted the idea that risks should be characterized by more than "a number," and that descriptive information is necessary to fully convey the nature and magnitude of a risk:

Often, when risk information is presented to the ultimate decision-maker and to the public, the results have been boiled down to a point estimate of risk. Such "short hand" approaches to risk assessment do not fully convey the range of information considered and used in developing the assessment. In short, informative risk characterization clarifies the scientific basis for EPA decisions, while numbers alone do not give a true picture of the assessment.

This principle was confirmed in the 1994 National Research Council (NRC) report, "Science and Judgment in Risk Assessment," which addressed the Agency's approach to risk assessment. The NRC statement accompanying the report stated, "... EPA's overall approach to assessing risks is fundamentally sound despite often-heard criticisms, but the Agency must more clearly establish the scientific and policy basis for risk estimates and better describe the uncertainties in its estimates of risk." EPA's new and revised risk assessment guidelines, and updated risk characterization policy, will reflect the recommendations of the NRC. EPA has also undertaken additional activities in response to the NRC report (see attachment).

It is important to recognize the considerable range of risk assessments that EPA conducts. We do not follow a "one-size-fits-all" approach. EPA regulatory programs may require one or more components of a risk assessment; a "screening risk assessment"; or a full risk assessment. Because we have limited resources (personnel and funds), we tailor our analytic approach to fit the decision needed. At present, EPA estimates that it spends about 2 person-days to perform a typical risk assessment for a screening analysis. In comparison, the Agency now spends about just over 12 person-months to produce the typical risk assessment associated with a major rule.

In addition, statutory requirements for risk assessment vary. In the 24 years of EPA's existence, we have acquired, piecemeal, a large number of statutory mandates across a very large number of environmental problems.

The result has been regulatory programs with different levels of flexibility and different risk and cost analyses to consider. Virtually every statute EPA administers requires findings about hazard or risk to be made in regulatory decisions. Some statutory findings support decisions on criteria for allowable pollutant levels in the environment; findings of this kind typically call for criteria that prevent adverse effects on public health with an "adequate (or ample) margin of safety". Criteria for ubiquitous air pollutants such as ozone and for drinking water contaminants are of this kind.

**Example:** As an example, very few Clean Air Act rules require separate findings about risk, since most of them merely implement risk management decisions already made by the Congress. However, on those Clean Air actions that do require risk assessment and peer review,

EPA's procedures can be quite extensive. For example, for development of National Ambient Air Quality Standards (NAAQS), risk characterization is based on a comprehensive review of all scientific information on health and environmental effects. Quantitative risk assessments are conducted, when possible, based all relevant factors, including typical air quality scenarios, realistic patterns of exposure, and central tendency estimates of exposure-response relationships. Ranges of plausible upper and lower bounds are presented to the extent possible to reflect uncertainties and inherent variability in these factors. The compilation and evaluation of the underlying scientific information, methods for assessing exposure and quantifying and characterizing risk, and staff interpretations and conclusions are all subject to extensive peer review prior to the development of regulatory options.

### **Current practices relating to Cost-Benefit Analysis**

As required under the current Executive Order 12866, defined major rules and actions proposed or promulgated by EPA must include a Regulatory Impact Analysis (RIA). Among the several components included in this requirement is a benefit-cost analysis. Originally, as a consequence of Executive Order 12291 issued in 1981, the Office of Management and Budget (OMB) and EPA both subsequently issued operating guidelines on the preparation of RIAs. EPA's report, titled "Guidelines for Performing Regulatory Impact Analyses" was released in 1983, and continues to serve as the Agency's primary guidance document on the production of RIAs and benefit-cost analyses. The document goes into greater detail than the OMB guidelines, focusing on analytic details relevant to EPA's mission. Since release of the first document, there have been no major changes to the document. A series of technical appendices were produced to examine sub-parts of a benefit-cost analysis. Since 1981, approximately 250 draft and final RIA documents have been produced by the Agency.

We should note that both the White House and EPA are presently working to revise these guidelines. The White House process of revising the benefit-cost guidelines is being co-chaired by staff from the Council of Economic Advisors and Department of Transportation. All affected federal agencies have been participating in an open series of meetings on the content of a new guidance document that conforms to EO 12866. Simultaneously, EPA has convened a group of Agency staff to update EPA's version of the RIA guidelines document. The primary objectives in rewriting the EPA document include: to address the new regulatory review process that delegates more analytic responsibilities to program offices; to insure that documents on regulatory analysis are scientifically thorough and accurate; to meet commitments to integrate "hard sciences" (e.g., health and ecological risk assessment process) with the social sciences; to reflect advances in theory and applications that have occurred since 1983; and to include any other new information and components contained in EO 12866.

EPA, in consultation with OMB, determines which EPA rules and actions meet the current definition of major actions contained in EO 12866. This universe of rules is then subject to the benefit-cost requirements described in the guidance document. We should note that there are many other types of economic analyses other than benefit-cost analyses performed by the Agency.

Most are developed as a consequence of requirements contained in statutory language. Some statutes provide for the use of economic information in setting making decisions. For example, the Agency engages in a number of cost-effectiveness, risk-benefit, and economic impact analyses in support of Agency decisions. In general, the level of analytic and staff time necessary to produce these analyses is substantially lower than that required in benefit-costs analyses of major rules.

At present, the scope of the economic analysis conducted to support Agency actions corresponds closely with the importance this information can have in the decision process. For currently defined major actions, a more substantial benefit-cost analysis is conducted because potentially large amounts of society's resources may be required to implement the rule. For other actions having less impact on society, less detailed and sophisticated analyses are generally suitable. In many cases, the statute specifically states that economic information is not supposed to be used as a basis for the regulatory decision. As a result, a less detailed economic analysis is produced because scarce analytic and staff resources can be more efficiently used for other purposes (e.g., other analyses of major actions).

**Example:** EPA's current practice is to focus its cost/benefit analysis on those rules that have the most cost impact. For example, the 20 rules that account for most of the implementation costs of the Clean Air Act are accompanied by complete "Regulatory Impact Analyses" (RIAs). By focusing on the most costly rules, EPA can target its analytic resources on those rules with the biggest impact. In all cases, whether or not a full RIA is required, economic analysis is done to ensure that the rules carry out Congressional decisions cost-effectively.

### **Current peer review practices and published procedures**

Peer review activities at EPA span a broad range of Agency products, including grants and contracts, laboratory research programs, and work products used for agency decision-making. Within each of these categories, practices and procedures vary from program to program and, within any given program, they vary for different types of documents.

Currently, some peer reviews are mandated by statute (e.g., Science Advisory Board review of national ambient air quality standards, FIFRA Scientific Advisory Panel review of pesticide actions). Others are wholly self-initiated (e.g., ORD's recent dioxin analysis, the Risk Assessment Forum's risk assessment guidelines), and others are undertaken at the request of senior management (e.g., recent review relating to risk assessment for the WTI incinerator).

On June 7, 1994, Administrator Browner established an Agency-wide policy and formal implementation program for one important and broad category: "major scientifically and technically based work products related to Agency decisions." On October 1, 1994, program-

specific standard operating procedures (SOPs) implementing the new policy went into effect in each program and regional office.

Each SOP captures the three major features of EPA's Peer Review Policy. First, each outlines principles and procedures relating to peer review of major scientific and technical work products related to Agency decisions, which include Agency work on health, ecology, engineering, economics and other technical issues.

This work is frequently used as the scientific and technical basis for Agency regulatory and policy decisions. The regulatory decisions, in turn, receive broad public review through the notice and comment process.

Second, each SOP vests responsibility and accountability for the conduct of peer review with the appropriate EPA Assistant and Regional Administrators. To that end, each SOP includes a list of candidate work products for peer review in FY 1995.

Third, the new procedures recognize both internal and external independent experts as peer reviewers. The SOPs explain that external experts are more appropriate for particularly novel, complex, costly or controversial issues. In other cases, internal agency experts may be appropriate. In both cases, relevant expertise and independence are critical requirements, as are the absence of bias and conflict-of-interest.

In addition to this new initiative for work product peer review, EPA is working closely with the National Science Foundation and the National Research Council on peer review for grants, contracts, internal EPA laboratory research and other elements of the Agency's total research program. The new procedures under development will expand and improve peer review for these aspects of EPA's work, with special emphasis on broader and more consistent application of established peer review principles and procedures.

These new initiatives complement existing EPA peer review activities by applying peer review processes to additional EPA offices and products, and by augmenting and improving current peer review activities.

EPA's peer review policy for science applies equally to economics. That is, scientific, engineering, and economic documents or positions that are used to support a research agenda, regulatory program, policy position or other Agency decision are subject to the Agency's Peer Review Policy.

**Example:** An example of EPA's current peer review practices can be found in the first and second reports to Congress on the Great Waters Study, which assesses the impacts of deposition of air pollutants to major aquatic ecosystems. Peer review is an extremely important issue for the program. The science used for the reports must be state-of-the-art because of the significant policy and regulatory implications to the assessments developed from that science. For the first report to Congress, teams of scientists, mostly academic, drafted scientific synthesis

documents to address each of the three major scientific questions for the program. These documents were then made available to a broad set of scientific experts from academia, U.S. and Canadian governments, and industry and environmental groups, who came together in a peer-review workshop to evaluate and comment on the documents for their revision. The resulting documents served as supporting documentation for the report. The second report to Congress is being developed with a supporting technical document that is to be a special publication for us by the Society of Environmental Toxicology and Chemistry (SETAC), a well-respected international scientific society. This work will undergo the same rigorous peer review process which SETAC requires of articles published in their journal.

4. **If enacted into law, how would the Act affect the Agency's present practices as described in question 3? If compliance with the Act would require additional resources in carrying out such practices, please estimate the additional resources (in terms of dollars and personnel) that would be required to carry out the provisions of the Act.**

Title III will have a number of different impacts on how we currently conduct risk assessments, peer reviews and cost-benefit analyses. It will first affect how we conduct these assessments, and then it will impact how many of these assessments we will do.

**Freezing the Science:** First, it has a single prescriptive formula for what must be included in a risk assessment and a risk characterization, describes precisely how a peer review must be done, and has a long list of items that must be included in a cost-benefit analysis and, under Title VII, a Regulatory Impact Analysis. In many cases, such analyses are not necessary for a decision, and will result in more inefficient and costly government actions. As we've said previously, Title III and Title VII prescribe a "one-size-fits-all" regulatory approach, one that will result in bureaucratic delay and the wasteful expenditure of private sector -- and government -- resources.

The major impact of the Act would be to specify approaches to risk assessment that may be inconsistent with the Agency's need for flexibility. The Act would require levels of analysis that would go beyond the needs of program-specific decisions. It has the potential to freeze the science at the 1994 level of understanding -- or earlier.

As we all know, science does not stand still. As more is learned about the biological effects of environmental contaminants generally and about effects and exposure to a particular contaminant, our risk assessment tools will be updated. At the present time our understanding of biological mechanisms or action of chemicals is growing rapidly. The development of the science of risk assessment must remain flexible in order to progress as knowledge of underlying phenomena improves. As progress occurs, risk estimates will change for individual contaminants. This will be disconcerting to those who have treated estimates as facts, but, in truth, should be understood as part of the evolution of the science and as adding to, not detracting from, the credibility of the science.

The methods and scientific basis of risk assessment will change and improve, as they have in the two decades of EPA's existence. The NAS/NRC report "Science and Judgment in Risk Assessment" will play an important role. While the report was mandated by the Congress under Section 112 of the Clean Air Act to particularly address the assessment of risks associated with exposure to hazardous air pollutants, it also applies to the conduct of risk assessment generally. The report points to changes that will improve current risk assessment practices, to basic research that will improve the science in the long run, and to near term technical developments that should

be supported. The EPA's newly chartered Science Policy Council, which is chaired by the Deputy Administrator, has been charged to plan activities for improving risk assessment methods in view of the recommendations of the report.

Our view is that the methods of conducting risk assessments must change continually to incorporate new knowledge gained from basic research and, accordingly, guidance for conducting risk assessments must not become a set of inflexible rules.

In addition, it is now very difficult to quantify all of the benefits of regulations, particularly the benefits of protecting ecological systems.

**Increasing the Numbers:** Second, it will require many more risk assessments, cost-benefit analyses, and peer reviews than current practices. In the answer to question 2, we estimated the increased number of risk assessments that EPA will have to conduct to meet the requirements of Title III -- even if the rule does not require a risk assessment to make a decision. There are many different reasons why EPA conducts a risk assessment, and the intensity of the assessment is gauged to the type of decision needed. Some assessments (e.g., review of many Premanufacture Notifications) are very brief and are completed in a day or two. Others, for example, the recent reassessment of dioxin, may take years to complete. By prescribing what an assessment, peer review, and cost-benefit analysis must contain, many of our current quick assessments will become unduly complex, cumbersome, and costly.

**Risk Assessment Costs:** EPA's rough estimate is that the number of full-blown, major risk assessments we would have to conduct if Title III is enacted would increase to about 2800 a year, up from 38 currently -- a very significant increase. Such an increase has a major impact on personnel and dollars needed to complete these risk assessments. In our answer to question 6, we have presented a detailed breakdown of cost and resource estimates. EPA estimates that it would require an additional \$115 million a year to complete these risk assessments.

**Cost-Benefit Costs:** Currently we conduct cost-benefit analyses for all rules that are undergoing a Regulatory Impact Analysis -- only about 15% of our current rules. Under Title III, we will have to conduct a cost-benefit analysis for all rules with impacts over \$25 million. However, we will also have to conduct such an analysis as part of an RIA, which has a threshold of \$1 million or 100 people affected. Thus the number of cost-benefit analyses would skyrocket to about 90% of all of our rules annually. Our rough estimates show that our costs will increase to about \$50 million annually -- just for the cost-benefit analysis.

**Peer Review Costs:** Likewise the personnel and costs for peer review would increase. We estimate that EPA would need to allocate, on an annual basis, an additional \$5 million in personnel costs (equivalent to approximately 62 additional FTEs), and an additional \$16 million in extramural costs.

**Example:** Under H.R. 9, in addition to the 20 air rules now requiring full RIAs, 149 more

rulemakings would require them. In addition, all of these rules would require risk assessments. Analytical costs would soar: the combined cost of each risk assessment and cost/benefit analysis would be about \$1,600,000 per rule; conducting both of these analyses for the additional 149 rulemakings would cost the Agency almost \$240 million dollars over the development cycle for those rules. On an annual basis, this would amount to an increase of about \$75 million per year; about \$35 million of this is for the 450 new FTEs that would be required; the remainder is contract support. This is about an eight-fold increase in analytical costs, and represents a required increase in overall resources for the air office of about 15% in dollars and 23% in FTE.

The result of all these provisions together would be years of delays even if agency resources were increased by the vast amounts that would be required. With resources held constant or cut, paralysis would be inevitable. And all of this would be redundant effort, revisiting risk and cost/benefit issues already settled in the Clean Air Act.

**5. How does the Agency obtain the information it uses to prepare risk assessments, cost-benefit analyses, or risk characterizations? Does the Agency rely in part upon the private sector in providing the information needed by the Agency to conduct such assessments or analyses? If so, would the Act require the Agency to obtain additional information from the private sector in order to comply with the Act's requirements?**

EPA obtains information for risk assessments, risk characterizations, and cost-benefit analyses from both the public and the private sector. Much of the data comes from the industries being regulated. The Agency also relies heavily on information developed in academic, government and industry studies and published in the peer-reviewed literature. In addition, it relies on data submitted under information collection rules such as Section 8 of the Toxic Substances Control Act. Several statutes (e.g. TSCA, FIFRA) require industries responsible for chemical or product manufacture to develop data. EPA has authority under other statutes, such as the Clean Air Act, to require industries to supply information.

The economic data collected and used in the Agency's analyses comes from a variety of sources. They include EPA's own industrial and household surveys of economic behavior (much of which is confidential), and primary and secondary data produced by other governmental and private sources on the activity in these sectors. EPA also surveys private firms to estimate the costs to the private sector of complying with environmental standards. The analysis of this data is performed by both EPA staff and consultants under contract to EPA.

H.R. 9 would require a vast increase in the amount of information demanded of the private sector. While cost information is now developed for some of these rules, EPA would have to gather additional data from the private sector to comply with this interpretation of H.R. 9.

However, while requiring all this new data, H.R. 9 would also prevent the Agency from collecting it: Section 5202 reduces the amount of information Agencies are allowed to collect by about 20% over the next four years.

6. **Please identify the regulations expected to be proposed or promulgated in the next two years which would require a Regulatory Impact Analysis under Title VII, an analysis of risk reduction benefits and costs or a certification under Subtitle B of Section 3201, or a peer review under Section 3301. What additional procedures would the Agency be required to follow to issue such regulations if the Act were enacted into law? Would the Act permit judicial review of agency actions beyond what is presently permitted under the Administrative Procedures Act? Please estimate the additional time and resources that would be necessary to complete the expected rulemaking following the required procedures. If the Agency is subject to court-ordered or statutory deadlines for completion of any such regulations, can the Agency comply with the Act and still meet such deadlines?**

H.R. 9 would significantly alter EPA's rulemaking practices. Currently, EPA performs detailed risk assessments and benefit-cost analyses for rules having an annual impact on the economy of \$100 million or more and therefore defined as major under EO 12866. EPA's current procedures are described in detail above, in the answer to question 3. Roughly about 15% of EPA's total number of rules currently require an RIA (excluding Pre-Manufacture Notifications -- PMNs -- for which we have little information, but which can number almost 2000 a year). Under H.R. 9, EPA would have to perform these detailed analysis for rules with an annual impact on the economy of as little as \$1,000,000 or that affect 100 people. Rough estimates show that EPA will have to perform detailed analyses under H.R. 9 for about 90% of our rules (again excluding PMNs) -- a significant increase over current practices. The individual rules under each category are listed in the Attachment to these questions.

In addition to requiring detailed RIAs for many more rules, Title VII of H.R. 9 could require the following new procedures:

- Obtain written approval of Director of OMB (Sec. 7005)
- Obtain certification from the Director, OMB that proposed major rules, summaries of proposed major rules and Regulatory Impact Analyses meet standards of clarity set out in Sec. 7006
- Comply with hearing requirements of Sec. 7003, for proposed rules.
- Provide pre-publication review of proposed rules by SBA (Sec. 6003)
- Provide memorandum of clear legal authority (EO 12291)

### **Estimated time to complete additional analyses**

In order to estimate the time necessary to complete the Agency's expected rulemakings, EPA developed estimates for the time necessary to complete each of four major requirements. These estimates assume that the Agency is provided with adequate resources to comply with the requirements.

#### **Regulatory Impact Analyses**

Assumptions: Historically, the Agency has only done the level of analysis contemplated under Title VII for rules having an annual impact in excess of \$100 million. Because it would now be required for all rules with an impact of \$ 1 million or more, the time necessary to complete the RIAs would be incremental to what the Agency has normally done for rules under \$100 million in annual impact on the economy. For rules over \$100 million in annual impact, the risk provisions of Title III will require additional analysis, such as central tendency estimates of toxicity and exposure components of risk assessment.

Rough Estimate: The average rule would require an additional **3-6 months** for the economic analysis. Because the risk assessment requirements would be new for many actions (e.g., effluent guidelines), they could require an additional **12 months**. Consequently the RIA could add **3-12 months** to the development time for rules that currently do not require an RIA, or 0-1 month for rules that currently require an RIA.

#### **Analysis of risk reduction benefits & costs under Sec. 3201.**

Assumptions: These analyses are required for rules with impact of \$ 25 million or more. The most significant new requirement of this section would be to analyze substitution risks.

Rough Estimate: Depending on the scope and complexity of the analysis and the number of substitutes that must be considered, the analysis could add from 3-6 months to the development of the rule. This assumes that the analysis begins during the development of the RIA, but additional time is required to analyze the potential effects after regulatory options have been identified.

#### **Obtain EPA certification of economic and risk information.**

Assumptions: EPA certification is only required for a final rule. The time to complete a peer review is not included in these estimates.

Rough Estimate: Each final rule would require an additional 1-3 months.

#### **Peer review**

**Assumptions:** Peer review is required only for rules with impacts in excess of \$25 million; and appropriate peer review experts are available.

**Rough Estimate:** An additional **3-6 months** would be necessary to comply with the peer review requirements. This would allow time to convene the peer review panel, conduct the review and draft their report to EPA.

Note, to estimate the additional time needed to develop any specific rule, and comply with these new requirements, we would determine the likely \$ impact of the rule to know which of these requirements would apply and sum the incremental times.

<b><u>Rule's Annual \$ Impact</u></b>	<b><u>Additional Development Time -- H.R. 9</u></b>	<b><u>Approximate # of rules</u></b>
>\$100 M	7 - 16 months	46
> \$25M	10 - 27 months	93
> \$1M	3 - 12 months	278

This estimate of additional rule development time is a substantial increase over the EPA's historic average development time for rules of approximately 36 months (18 months for proposal and 18 months for promulgation). As can also be seen, there is a substantial increase in the number of rules affected by these requirements.

There are several ways of interpreting the complex and uncertain aspects of implementing the provisions of H.R. 9 titles that affect risk assessment, economic analysis, and peer review. As a consequence, the data used to produce the figures presented below is undergoing continual review and may change as further analysis is performed by the Agency. However, in the interest of estimating possible costs to EPA of selected provisions in H.R. 9, we are providing this material in its current state.

Although the cost estimates below are very preliminary and subject to further refinement, EPA could be required to spend, on an annual basis, an additional \$78 million in personnel costs (equivalent to approximately 980 additional FTEs) and an additional \$142 million in extramural analytical costs to perform the requirements identified in the cited provisions of H.R. 9. These costs assume the level of regulatory activity set under the Regulatory Agenda, including statutory deadlines and consent decrees. The baseline level of intramural (FTE) and extramural (analytic) resources now devoted to these is approximately \$55 million and \$65 million per year, respectively. Therefore, these requirements would require a doubling of staff (about 140% increase over the FTE base) and a tripling of extramural resources (about 218% increase over the analytic base) allocated to these activities.

**Estimated Annual Costs to EPA to Comply with  
Provisions of H.R. 9, Titles III, VI and VII  
(Costs in Millions of 1995 Dollars)**

	H.R. 9 New <u>Required FTE \$</u>	H.R. 9 New <u>Required Analytic \$</u>	TOTAL <u>New Requirements \$</u>
Risk Assess-Revisit & Expanded	\$36	\$79	\$115
RA Peer Review	\$3	\$10	\$13
Benefit-Cost Analysis	\$18	\$32	\$50
BC Peer Review	\$2	\$6	\$8
Comments/Responses	\$6	\$13	\$19
OMB Review	<u>\$13</u>	<u>\$2</u>	<u>\$15</u>
Total	\$78	\$142	\$220

Note that several categories of costs to EPA in meeting the H.R. 9 provisions have not yet been estimated. Therefore, absent this information, the figures may be underestimates of the total costs

**Example:** Under the H.R. 9 criteria, virtually all 169 Clean Air Act rulemakings currently underway would require a Regulatory Impact Analysis under Title VII. The primary impact of this provision would be increased analytical costs.

Under Section 3201, about 37 of these rules would require an analysis of risk reduction benefits and costs and a certification. This provision would probably have relatively little additional impact, since they mostly duplicate requirements implied under Title VII.

Under Section 3301, about 18 of these rules would require peer review. The primary additional impact would be the time and resources necessary to select and convene the peer review panels, receive their findings, and conduct any necessary reanalysis and rework. The most important impact would probably be added time, since rulemakings would be held up until peer review issues got resolved.

**Judicial Review:** The Act has the potential to vastly expand the substantive areas and the procedures arguably subject to traditional Administrative Procedures Act review, through the imposition of many new requirements. Furthermore, the requirement for a statement of clear legal authority -- incorporated through Title VII's codification of Executive Order 12291 -- has the potential to be interpreted by the courts in a variety of ways.

Title III itself is silent on the question of judicial review of any of its three provisions (risk assessment, risk/benefit analysis, and peer review). Any final regulation or action that relies on a risk assessment or risk/benefit analysis performed pursuant to Title III would currently be reviewable under the Administrative Procedures Act under the traditional standard of review for regulations and other final agency actions. It is likely under Title III that any person interested in challenging a final regulation or action could raise issues related to whether the Agency complied in all respects with subtitled B and C; a reviewing court may find that failure to comply with any

of the risk/benefit balancing or peer review requirements of those subtitles is sufficient grounds for reversal of the regulation or action. Portions of Subtitle B (and also of Title VII of HR 9) raise a question as to whether a person could challenge the issuance of a proposed regulation if the person asserts that the proposal failed to comply with the requirements of HR 9. The same review issues are raised by Subtitle A (dealing with the risk assessment process), but that subtitle raises additional issues as well. It is unclear whether the guidelines for developing assessments would themselves be subject to judicial review under the traditional standard of review applied to regulations; it is likely that litigation would be necessary to resolve this issue. Similarly, it is not clear from Subtitle A whether a risk assessment itself is challengeable whenever it is released to the public, or whether an underlying final agency action (and only to the extent that it influences the final action). Again, litigation to resolve these issues seems like a likely result.

**Court-Ordered Deadlines:** In most cases, court-ordered or statutory deadlines are very tight. It will be extremely challenging to meet these deadlines while complying with H.R. 9's many new substantive provisions, and EPA would be required to seek relief.

## QUESTION 6 (cont'd)

[January 25, 1995]

OPPTS Related Actions Expected Over the Next 2 Years - Estimated Impact of HR-9 Requirements

Title of Action	Impacts 100 people or is >1 mil (RIA)?	Impact is >25 mil?	Impact is >100 mil?
Proposed Rule; Facility Coverage Amendment; Toxic Chemical Release Reporting; Community Right-to-Know [Rin 2070-AC71]	Yes	Yes	Yes
Final Rules; Several Actions Related to the Proposed Chemical List Expansion; Toxic Release Reporting; Community Right-to-Know [Rin 2070-AC47]	Yes (taken altogether)	Yes	
Proposed Rule; Lead Hazard Standards (Section 403) [Rin 2070-AC63]	Yes	Yes	
Final Endangered Species Protection Program Policy [Rin 2070-AC42]	Yes	Yes	
Final Group A; Revocation of Pesticide Food Additive Tolerances Subject to Delaney Clause [Rin 2070-AC55]	Yes	Yes	Yes
Final Group B/D; Revocation of Pesticide Food Additive Tolerances Subject to Delaney Clause [Rin 2070-AC55]	Yes	Yes	Yes
Proposed Group C; Revocation of Pesticide Food Additive Tolerances Subject to Delaney Clause [Rin 2070-AC55]	Yes	Yes	Yes
Final Rule; Revision to the Training Provisions for Workers; Pesticide Worker Protection Standard [Rin 2070-AC69]	Yes		
Final Rule; Revision of Crop Advisor Requirement; Pesticide Worker Protection Standard [Rin 2070-AC82]	Will impact >100 people, but impact is regulatory relief.		

Title of Action	Impacts 100 people or is >1 mil (RIA)?	Impact is >25 mil?	Impact is >100 mil?
Final Rule; Hazard Communication; Pesticide Worker Protection Standard [Rin 2070-AC34]	Yes		
Final Rules; Amendments to the Premanufacture Notification (PMN) Rule [Rin 2070-AC14]	Impacts >100 people, some costs, but mostly reg relief.		
Proposed Rule; Deletion of Isopropyl Alcohol; Toxic Chemical "Release Reporting; Community Right-to-Know [Rin 2070-AC77]	May impact 100 people, but this would eliminate a burden and is reg relief.		
Proposed Guidance Under E.O. 12873: 503 on Environmental Preferable Products [Rin 2070-AC78]	N/A, because this applies to Federal Agencies only.		
Final Rules; Lead-Based Paint Activities Rules; Training, Accreditation and Certification Rule and Model State Plan Rule [Rin 2070-AC64]	Yes	Yes	Yes
Final Rule; Mandatory Pollution Prevention Reporting for Toxic Release Inventory (TRI) [Rin 2070-AC24]	Yes	Yes	Yes
Proposed Rule; Hazardous Air Pollutants (aka Clean Air Act Section 112 Chemicals); Multi-Chemical Endpoint Test Rule [Rin 2070-AC76]	Yes	Yes	
Final Rules; Polychlorinated Biphenyls (PCBs) Disposal Amendments [Rin 2070-AC01]	Impacts >100 people, but would provide \$4 billion in savings, while imposing only \$12 mil for recordkeeping.		

Title of Action	Impacts 100 people or is >1 mil (RIA)?	Impact is >25 mil?	Impact is >100 mil?
Various Actions (Proposed & Final) in Response to Petitions Received to Add or Delete Chemicals From the List of Toxic Chemicals Subject to Toxic Release Reporting Under EPCRA Section 313 (Rin 2070-AC00)	May impact >100 people, but only has any \$ impact if its an addition. If a deletion, it eliminates a requirement and qualifies as reg relief.	An addition could have an impact >25 mil, but its rare.	
Proposed Rule; Asbestos; Significant New Use Rules on National Program Chemicals [Rin 2070-AC37]	Don't expect it to impact anyone - this substance is already banned.		
Proposed Rule; Lead; Significant New Use Rules on National Program Chemicals [Rin 2070-AC37]	Too early in the process -- Impact is unknown at this time.		
Proposed Rule; TSCA Requirements for the Disposal of Lead-Based Abatement Waste [Rin 2070-AC72]	Impacts >100 people, but impact should result in a net savings.		
Proposed Rule; Lead-Based Paint Activities, Training & Certification: Renovation & Remodeling [Rin 2070-AC83]	Yes	Yes	Yes
Final TSCA Section 8(e) Policy Clarification [Rin 2070-AC80]	N/A, impacts >100 people, but imposes no new burdens.		
Final Rule; Classification of Certain Pesticides for Restricted use due to Ground-Water Concerns [Rin 2070-AC33]	Yes		
Proposed Rule; Pesticides and Groundwater State Management Plan (SMP) Regulation [Rin 2070-AC46]	Yes	Yes	
Final Rule; Pesticide Management & Disposal (Phase I) [Rin 2070-AC81]	Yes	Maybe	

Title of Action	Impacts 100 people or is >1 mil (RIA)?	Impact is >25 mil?	Impact is >100 mil?
Proposed Rule; Pesticide Occupational Cancer Risk Level of Concern Policy [Rin 2070- 2070- ]	No. This is explains an internal policy.		
Final Policy & Procedure for Notification to the Agency of Stored Pesticides with Cancelled or Suspended Registration [Rin 2070-AC08]	Yes	Probably	
Proposed Rule; Microbiological Water Purifiers; Labeling Claims [Rin 2070-AC43]	Yes		
Proposed Rule; Revision of the Data Requirements for Pesticide Registration (40 CFR Part 158) [Rin 2070-AC12]	Yes	Yes	Maybe
Final Rule; Restricted Use Criteria For Pesticides in Groundwater [Rin 2070-AB60]	Yes	Unknown	
Final Rule; Standards for Pesticide Containers and Containment; Pesticide Management and Disposal (Phase II) [Rin 2070-AB95]	Yes	Yes	
Proposed Rule; Certification of Pesticide Applicators [Rin 2070-AB75]	Yes		
Proposed Rule; Amendments to the Asbestos- Containing Materials in School Rule [Rin 2070-AC62]	Yes	Probably	
Final Rule; Amendments to the Asbestos Worker Protection Rule [Rin 2070-AC66]	Yes		
Final Rule; Amendment to the TSCA Section 8(a) Comprehensive Assessment Information Rule [Rin 2070-AC19]	Yes	Maybe	
Proposed Rule; ATSDR Substances Test Rule [Rin 2070-AB79]	Yes	Yes	

Title of Action	Impacts 100 people or is > 1 mil (RIA)?	Impact is >25 mil?	Impact is >100 mil?
Proposed Rule; Chemical Fate & Environment Effects (aka Bioaccumulators); Multi-Chemical Endpoint Test Rule [Rin 2070-AC36]			
Final Decision on Test Rules; Aryl Phosphates (ITC List 2,18,3,22,27) [Rin 2070-AB94]	Yes	Yes	
Final Rule; Developmental and Reproductive Toxicity; Multi-Chemical Endpoint Test Rules [Rin 2070-AC27]	Yes	Yes	
Various Proposed & Final Decisions on Test Rules (Actions in response to recommended testing by the Interagency Testing Committee [Rin 2070-AB07])	Yes	Yes	
Various Final Test Rules; Chemical Specific Based on Enforceable Consent Agreements [Rin 2070-____]	Only impacts parties to the agreement, but impact could be more than 1 mil.	Possibly	
Various (proposed & final) Chemical Specific SNURs to Extend Provisions of TSCA Section 5(e) Consent Orders [Rin 2070-AB27]	May impact 100 people, but cost impact is undeterminable, because no one has ever submitted a SNUR Notice.		
Various (proposed & final) Follow-Up Rules for Existing Chemicals (Chemical Specific) [Rin 2070-AA58]	"		
Various (proposed & final) Follow-Up Rules on Non-5(e) New Chemical Substances (Chemical Specific) [Rin 2070-AA59]	"		
Final Rule; Acrylate Compounds; Generic Significant New Use Rule [Rin 2070-AB56]	No		
Proposed Rule; Child-Resistant Packaging Regulations (Revision) [Rin 2070-AB96]	Yes		

Title of Action	Impacts 100 people or is >1 mil (RIA)?	Impact is >25 mil?	Impact is >100 mil?
Proposed Rule; Exemption of Sterilant Pesticide Products from Regulations Under FIFRA [Rin 2070-AC58]	Impacts >100 people, but impact is regulatory relief.		
Proposed Rule; FIFRA Books and Records of Pesticide Production and Distribution (Revision) [Rin 2070-AC07]	Yes	Maybe	
Final Rule; Flammability Labeling Requirement for Total Release Foggers [Rin 2070-AC60]	Yes		
Final; Herbicide Use on Herbicide Tolerant Plants Policy Statement [Rin 2070- ]	Impacts >100 people, but impact may not be greater than 1 mil.		
Proposed Rule; Interpretation of Raw Agricultural Commodity [Rin 2070-AC54]	Yes		
Final Rule; Lead-Based Paint Hazard Disclosure Requirement at the Transfer of Target Housing (Section 1018) [Rin 2070-AC75]	Yes	Yes	
Lead-Based Paint Hazard Disclosure Requirements at Renovation of Target Housing (Section 406) [Rin 2070-AC65]	Yes	Yes	
Proposed Rule; Exemption From Pesticide Regulatory Requirements [Rin 2070-AC67]	Impacts >100 people, but impact is regulatory relief.		
Final Rule; Pesticide Tolerance; Portion of Food Commodities to be Analyzed for Pesticide Residue [Rin 2070-AC45]	Yes		
Advanced Proposed Rule; Pesticide; Tolerance Program Revisions [Rin 2070-AC74]	Yes	Probably	

Title of Action	Impacts 100 people or is >1 mil (RIA)?	Impact is >25 mil?	Impact is >100 mil?
Final Rule; Pesticide Tolerances; Revision of Crop Groups [Rin 2070-AC52]	Impacts >100 people, but impact is regulatory relief.		
Final Rule; Polychlorinated Biphenyls (PCBs); Applications for Exemptions from the Ban on Manufacturing, Processing, and Distribution [Rin 2070-AB20]	No, this only impacts the applicant & impact is <1 mil.		
Final Rule; Polychlorinated Biphenyls (PCBs) Transformer Reclassification Rule [Rin 2079-AC39]	Yes	Probably	
Proposed Rule; Procedure to Make Restricted Use Pesticides Available to Noncertified Persons for Use by Certified Applications [Rin 2070-AB48]	Yes		
Final Rule; Regulation of Plant-Produced Pesticides under FIFRA and FFDCA [Rin 2070-AC02]	Yes		
Final Rule; Lead Fishing Sinkers; Regulatory Investigation of Lead Products Under TSCA [Rin 2070-AC21]	Yes	Yes	Yes
Final Rule; Reporting Requirements for Risk/Benefit Information under FIFRA [Rin 2070-AB50]	Yes		
Final Rule; Rulemaking Concerning Certain Microbial Products ("Biotechnology") Under TSCA [Rin 2070-AB61]	Yes	Yes	
Final Rules; Section 8(a) Preliminary Assessment Information Rules [Rin 2070-AB08]	May impact 100 people, but the impact is <1 million.		
Final Rules; Section 8(d) Health and Safety Data Reporting Rules [Rin 2070-AB11]	May impact 100 people, but the impact is <1 million.		

Title of Action	Impacts 100 people or is >1 mil (RIA)?	Impact is >25 mil?	Impact is >100 mil?
Final Rule; Refractory Ceramic Fibers; Significant New Use Rule on National Program Chemicals [Rin 2070-AC37]	Probably impacts >100 people, but impact is unknown.		
Proposed Rule; TSCA Chemical Use Inventory Rule [Rin 2070-AC61]	Yes	Probably	
Final Rule; Use of Acrylamide and N- Methylolacrylamide (NMA) for Grouting [Rin 2070-AC17]	Yes		
Proposed Rule; Acute Toxicity Criteria for Pesticide Labelling [Rin 2070- ]	Yes		
Final Rule; Asbestos Model Accreditation Plan [Rin 2070-AC51]	Yes	Yes	Yes
Notice of TSCA Sec.4 Reimbursement Period & TSCA Sec.12(b) Export Notification Period Sunset Dates [Rin 2070- ]	Impacts >100 people, but impact is expected to be minimum, if any.		
Proposed Rule; Pesticide Resistance Management [Rin 2070- ]	Yes		
Proposed Rule; Pesticide Hazard Labeling [Rin 2070- ]	Yes		
Proposed Rule; Prescription Use of Pesticides [Rin 2070- ]	Yes		

## QUESTION 6 (cont'd)

## OFFICE OF AIR AND RADIATION

## Clean Air Act (CAA)—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
* 4103	SAN No. 3448. NAAQS: Particulate Matter (Review) .....	2060-AE88
4104	SAN No. 3468. Establishment of Lesser Quantity Emission Rates for Hazardous Air Pollutants .....	2060-AE98
* 4105	SAN No. 3549. NESHAP: Petroleum Refineries - FCC Units, Reformers and Sulfur Plants .....	2060-AF28
4106	SAN No. 3344. NESHAP—Chromium Chemical Manufacturing .....	2060-AE42
4107	SAN No. 3552. Regional Haze Protection .....	2060-AF32
4108	SAN No. 3037. Report to Congress and Prioritized Category List for Regulation of VOC Emissions from Consumer and Commercial Products .....	2060-AE24
4109	SAN No. 3389. Fuels and Fuel Additives Waiver Application Criteria .....	2060-AE58

## Clean Air Act (CAA)—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
4110	SAN No. 2909. Revisions to the New Source Review Regulations .....	2060-AD13
* 4111	SAN No. 2961. Locomotive Emissions Standards .....	2060-AD33
4112	SAN No. 3111. Prohibition of Leaded Gasoline for Highway Use .....	2060-AD55
4113	SAN No. 3369. Federal Operating Permit Rules .....	2060-AD85
4114	SAN No. 3286. Mobile-Stationary Source Trading Program .....	2060-AD85
4115	SAN No. 3259. New Source Review (NSR) Reform (Reg Plan Seq. No. 151) .....	2060-AE11
4116	SAN No. 3186. Amendments to the Emission Defect Reporting Requirements .....	2060-AE16
4117	Inspection/Maintenance Program Requirements—Onboard Diagnostic Checks .....	2060-AE19
4118	SAN No. 3263. Performance Warranty and Inspection/Maintenance Test Procedures .....	2060-AE20
4119	SAN No. 3262. Inspection/Maintenance Recall Requirements .....	2060-AE22
4120	SAN No. 3355. Federal Implementation Plans To Achieve the National Ambient Air Quality Standard for Ozone in the Sacramento Metropolitan Area, SCAQMD, and Ventura County, California Nonattainment Areas .....	2060-AE26
4121	SAN No. 3302. Consolidated Emission Reporting .....	2060-AE32
4122	SAN No. 3314. Addition of Test Method 205 to Appendix M of 40 CFR Part 51 .....	2060-AE33
* 4123	SAN No. 3353. NAAQS: Ozone (Review) (Reg Plan Seq. No. 162) .....	2060-AE37
4124	SAN No. 3354. State Implementation Plan Completeness Criteria .....	2060-AE98
4125	SAN No. 3278. Standards for Emissions from Ethanol-Fueled Motor Vehicles and Motor Vehicle Engines .....	2060-AE37
4126	SAN No. 3407. Amendment of Method 23: Measurement of Dioxin Emission from Stationary Sources and Method 301: Field Validation of Pollution Measurement Methods for Various Media .....	2060-AP08

\* indicates rule that may have annual economic impact greater than \$100 million.

## EPA

## Clean Air Act (CAA)—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
4127	SAN No. 3526. Ozone Transport Commission; Emission Vehicle Program for the Northeast Ozone Transport Region (Reg Plan Seq. No. 183)	2060-AF15
4128	SAN No. 3474. Ammonia Test Method, 40 CFR Part 51, Appendix M	2060-AF23
4129	SAN No. 3473. Test Method 302, Appendix M, 40 CFR Part 51	2060-AF22
4130	SAN No. 3472. Technical Corrections to 40 CFR 60, Appendix A and to 40 CFR 61, Appendix	2060-AF24
4131	SAN No. 3082. NESHAP: Ferroalloy Industry	2060-AF28
4132	SAN No. 3553. Requirements for Preparation, Adoption, and Submittal of Ozone State Implementation Plans	2060-AF34
4133	SAN No. 3516. Comprehensive Radiation Waste Management Rule	2060-AF41
4134	SAN No. 3569. Federal Implementation Plan to Control Emissions From Two Power Stations Located on Navajo Nation Lands	2060-AF42
4135	SAN No. 3572. Acid Rain Program: Revisions to Applicability, Exemptions, Allocations, and Small Diesel Refineries	2060-AF45
4136	SAN No. 3574. Acid Rain Program: Revisions to the Permits Regulations Under Title IV of the Clean Air Act to Make Technical Corrections	2060-AF47
4137	Control of Air Pollution from Aircraft and Aircraft Engines; Emission Standards and Test Procedures	2060-AF50
4138	SAN No. 3519. Conventional Gasoline Marker	2060-AF53
4139	SAN No. 1004. NAAQS: Nitrogen Dioxide (Review)	2060-AF54
4140	SAN No. 3016. Revise Capture Efficiency Guidelines	2060-AF54
4141	SAN No. 3470. Supplement D to the Guideline on Air Quality Modeling	2060-AF01
4142	SAN No. 2719. Medical Waste Incinerators (Reg Plan Seq. No. 154)	2060-AF02
4143	SAN No. 2916. NSPS: Municipal Waste Combustion—Phase II and Phase III (Reg Plan Seq. No. 155)	2060-AF00
4144	SAN No. 3106. NSPS for Sulfur Dioxide (SO <sub>2</sub> ) - Revision	2060-AF04
4145	SAN No. 3379. NSPS: Starch Production Facilities	2060-AE65
4146	SAN No. 2719. NSPS: Medical Waste Incinerators	2060-AE73
4147	SAN No. 2892. NESHAP: Asbestos Processing	2060-AE81
4148	SAN No. 3105 (was 2914). Integrated NESHAP and Effluent Guideline: Pulp and Paper	2060-AF03
4149	SAN No. 2965. NESHAP for Wood Furniture Manufacturing	2060-AF07
4150	SAN No. 3373/2993. Radionuclide Major Source Definition	2060-AF06
4151	SAN No. 3077. NESHAP: Printing/Publishing Industry	2060-AF09
4152	SAN No. 3166. NESHAP: Polymers and Resins, Group I	2060-AF06
4153	SAN No. 3074. NESHAP: Surface Coating Operations in Shipbuilding and Ship Repair	2060-AF08
4154	SAN No. 3159. NESHAP for Off-Site Waste Operations	2060-AE05
4155	SAN No. 3215. NESHAP: Mineral Wool Production Industry	2060-AE08
4156	SAN No. 3229. NESHAP: Oil and Natural Gas Production	2060-AE34
4157	SAN No. 3228. National Emission Standard for Hazardous Air Pollutants (NESHAP) for Polymers and Resins, Group III	2060-AE36
4158	SAN No. 3187. NESHAP: Polymers and Resins, Group IV	2060-AE37
4159	SAN No. 3303. NESHAP—Phosphoric Acid Manufacturing	2060-AE40
4160	SAN No. 3345. NESHAP—Steel Pickling, HC1 Process	2060-AE41
4161	SAN No. 3343. NESHAP—Iron Foundries and Steel Foundries	2060-AE43
4162	SAN No. 3304. NESHAP—Phosphate Fertilizers Production	2060-AE44
4163	SAN No. 3340. NESHAP—Primary Copper Smelters	2060-AE46
4164	SAN No. 3342. NESHAP—Wood Treatment Industry	2060-AE47
4165	SAN No. 3346. NESHAP—Integrated Iron and Steel	2060-AE48
4166	SAN No. 3479. Amendments to Part 63 to Establish Provisions for Determining Potential to Emit	2060-AE53
4167	SAN No. 3123. NESHAP: Wool Fiberglass Manufacturing Industry	2060-AE75
4168	SAN No. 3072. NESHAP: Primary Aluminum Plants	2060-AE76
4169	SAN No. 3078. NESHAP: Secondary Aluminum Industry	2060-AE77
4170	SAN No. 3079. NESHAP: Portland Cement Manufacturing	2060-AE78
4171	SAN No. 3326. NESHAP: Reinforced Plastic Composites Production	2060-AE79
4172	SAN No. 3453. NESHAP: Combustion Sources in the Sulfite Pulp Industry	2060-AE80
4173	SAN No. 3408. NESHAP: Polyether Polyol Production	2060-AE81
4174	SAN No. 3452. NESHAP: Non-SOCMI Organic Chemical Production	2060-AE82
4175	SAN No. 3451. NESHAP: Pharmaceuticals Production	2060-AE83
4176	SAN No. 3450. NESHAP: Production of Agricultural Chemicals	2060-AE84
4177	SAN No. 3449. NESHAP: Chlorine Manufacturing	2060-AE85
4178	SAN No. 3338. NESHAP: Flexible Polyurethane Foam Production	2060-AE86
4179	SAN No. 3467. NESHAP: Primary Lead Smelters	2060-AE97
4180	SAN No. 3469. NESHAP: Manufacture of Tetrahydrobenzaldehyde	2060-AE99

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## Clean Air Act (CAA)—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
4181	SAN No. 2547. National Emission Standard for Radon Emissions from Phosphogypsum Stacks .....	2060-AF04
4182	SAN No. 3378. NESHAP: Manufacturers of Acrylic/Modacrylic Fibers .....	2060-AF06
4183	SAN No. 3465. NESHAP: Polycarbonates Production .....	2060-AF09
4184	SAN No. 3466. Delisting of Source Categories under 112(c): Stainless and Non-Stainless Steel Manufacturing and Electric Arc Furnace (EAF) Operation .....	2060-AF11
4185	SAN No. 3377. Publically Owned Treatment Works (POTW) Study .....	2060-AF26
4186	SAN No. 3548. NESHAP: Nylon 6 Production .....	2060-AF27
4187	SAN No. 3550. NESHAP: Baker's Yeast Manufacturing Industry .....	2060-AF30
4188	SAN No. 3551. Amendments to General Provisions for 40 CFR 63 .....	2060-AF31
4189	SAN No. 3459. Criteria and Procedures for Determining Transportation Conformity in Attainment Areas .....	2060-AE90
4190	Correction to Criteria and Procedures for Determining Transportation Conformity: Nitrogen Oxides Requirements for Areas with a 182 (f) Exemption .....	2060-AF25
4191	SAN No. 3281. VOC Regulation for Automobile and Truck Refinishing Coatings .....	2060-AE35
4192	SAN No. 3351. VOC Regulation for Architectural and Industrial Maintenance Coatings .....	2060-AE55
4193	SAN No. 2869. Revised Light-Duty Durability Procedures for Model Year 1999 and Later .....	2060-AE56
4194	SAN No. 3191. Cold Temperature Carbon Monoxide Emissions Averaging .....	2060-AE13
4195	SAN No. 3456. Tier 2 Emission Standards .....	2060-AE87
4196	SAN No. 3454. Control of Motor Vehicle Evaporative Emissions .....	2060-AE89
4197	SAN No. 3139. Amendment Concerning the Location of Selective Enforcement Audits of Foreign Manufactured Vehicles and Engines .....	2060-AD90
* 4198	SAN No. 3323. Review of the Federal Test Procedure for Emissions From Motor Vehicles and Motor Vehicle Engines (Reg Plan Seq. No. 158) .....	2060-AE27
4199	SAN No. 2727. Emission Design and Defect Warranty and Parts List .....	2060-AD56
4200	SAN No. 2728. Revisions to Regulations on Registration of Fuels and Fuel Additives .....	2060-AC74
* 4201	SAN No. 2769. Control of Air Toxics Emissions From Motor Vehicles (Reg Plan Seq. No. 157) .....	2060-AC75
4202	SAN No. 3091. "Substantially Similar" Definition for Diesel Fuels .....	2060-AD77
4203	SAN No. 3455. Standards for Methanol Vehicle Filnecks and Methanol Fuel Dispensers, and Specifications for Methanol Vehicle Fuel .....	2060-AE88
4204	SAN No. 3361. Emission Standards for New Nonroad Spark-Ignition Engines At and Below 19 Kilowatts (25 horsepower) (Phase 2) (Reg Plan Seq. No. 158) .....	2060-AE25
* 4205	SAN No. 3350. Emission Standards for Gasoline Spark-ignition and Diesel Compression-ignition Marine Engines .....	2060-AE54
4206	SAN No. 3458. Emission Standards for Nonroad Recreational Vehicles and Revision of On-highway Motorcycle Emission Standards .....	2060-AE91
4207	SAN No. 3173. Restrictions on Motor Vehicle and Non-Road Engines .....	2060-AD72
4208	SAN No. 3325. Urban Bus Pass/Fail Rate Rulemaking .....	2060-AE71
* 4209	SAN No. 2888. Acid Rain Nitrogen Oxides Control Regulation .....	2060-AD45
* 4210	SAN No. 3352. NSPS for Nitrogen Oxides (NOx) - Revision .....	2060-AE56
4211	SAN No. 3462. Protection of Stratospheric Ozone: Administrative Changes to the Final Rule to Phaseout Ozone Depleting Chemicals .....	2060-AE70
4212	SAN No. 3460. Protection of Stratospheric Ozone: Supplemental Rule to Amend Leak Repair Provisions, Equipment Standards and Scope of Chemicals to be Recycled Under Section 606 of the Amended CAA .....	2060-AE92
4213	SAN No. 3463. Protection of Stratospheric Ozone: Supplemental Rule to Amend Grandfathering Requirements for the Technician Certification Program for National Recycling .....	2060-AF05
4214	SAN No. 3555. Amendment to the MVAC Rule to Include All Refrigerants .....	2060-AF35
4215	SAN No. 3556. Protection of Stratospheric Ozone: Supplemental Rule Regarding a Recycling Standard Under Section 608 .....	2060-AF36
4216	SAN No. 3560. Amendment to the Refrigerant Recycling Rule to Include All Refrigerants .....	2060-AF37
4217	SAN No. 3537. Protection of Stratospheric Ozone: Supplemental Rule to Amend Leak Repair Provisions, Equipment Standards and Scope of Chemicals to be Recycled Under Section 606 of the Amended CAA .....	2060-AF32

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.

## Clean Air Act (CAA)—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
4218	SAN No. 2942. Enhanced Monitoring Program .....	2060-AD18
4219	SAN No. 2955. Registration and Testing of Lead Substitute Gasoline Additives .....	2060-AD29

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## Clean Air Act (CAA)—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
4220	SAN No. 2951. Emission Standards for Clean-Fuel Vehicles and Engines, Requirements for Clean-Fuel Vehicle Conversions and California Pilot Test Program	2060-AD32
4221	SAN No. 3009/3357. Acid Rain Opt-In Regulations	2060-AD43
4222	SAN No. 3018. Standards for Deposit Control Gasoline Additives	2060-AD71
4223	SAN No. 2939. Regulations Governing Awards Under Section 113(f) of the Clean Air Act	2060-AD81
4224	SAN No. 3221. Administration of the Clean Air Act and the Clean Water Act With Respect to Contracts, Grants, and Loans—List of Facilities Ineligible for Federal Procurement and Nonprocurement Programs	2060-AD83
4225	SAN No. 3285-2763. Emission Standards for Gaseous-Fueled Vehicles and Certification Procedures for Aftermarket Conversions	2060-AD86
4226	SAN No. 3261. Inspection/Maintenance Program Requirements—Provisions for Redesignation	2060-AE21
4227	SAN No. 2887. National Emissions Standards for Hazardous Air Pollutants as it Applies to Nuclear Power Reactors Licensed by the Nuclear Regulatory Commission	2060-AE38
4228	SAN No. 3148. NESHAPS Pertaining to Facilities Other Than Commercial Nuclear Power Reactors Licensed by the Nuclear Regulatory Commission (NRC) or by NRC Agreement States	2060-AE39
4229	SAN No. 3347. Protection of Stratospheric Ozone: Mobile Air-Conditioning Recover-Only Standard; Supplemental Rule	2060-AE52
4230	SAN No. 3319. Acid Rain Program, Revisions of Substitution and Reduced Utilization Regulations	2060-AE58
4231	SAN No. 3457. On-Board Diagnostics Service Information Available	2060-AE93
4232	SAN No. 3380. NSPS: Synthetic Organic Chemicals Manufacturing Industry - Wastewater	2060-AE94
4233	SAN No. 3500. Application of Mandatory Sanctions Under Title V of the Clean Air Act	2060-AE96
4234	SAN No. 3016. Addition of Methods 204, 204A - 204F for Measurement of VOC Emissions from Stationary Sources	2060-AF02
4235	Regulation of Fuels and Fuel Additives: Individual Foreign Refinery Baseline Requirements for Reformulated Gasoline	2060-AF13
4236	SAN No. 3259. New Source Review (NSR) Reform Rulemaking	2060-AF21
4237	SAN No. 3570. Acid Rain Program: Revisions to the Administrative Appeal Regulations Under Title IV of the Clean Air Act	2060-AF43
4238	SAN No. 3573. Acid Rain Program: Deletion of Certain Units	2060-AF48
4239	Technical Amendments to Evaporative Emission Procedure	2060-AF49
4240	SAN No. 3448. Revisions to Part 35, Subpart A Section 105 Air Grant Regulations	2060-AF03
4241	SAN No. 1002. NAAQS: Sulfur Dioxide (Review)	2060-AA81
4242	SAN No. 2535. NSPS: Municipal Solid Waste Landfills	2060-AC42
4243	SAN No. 3382. New Source Performance Standards for Cold Cleaning Operations	2060-AF08
4244	SAN No. 3515. Revision to Standards of Performance for New Stationary Sources: Automobile and Light Duty Truck Surface Coating Operation	2060-AF14
4245	SAN No. 2841. NESHAP: Chromium Electroplating	2060-AC14
4246	SAN No. 2484. NESHAP: Ethylene Oxide From Commercial Sterilization	2060-AC28
4247	SAN No. 1695. NESHAP: Halogenated Solvent Cleaning	2060-AC31
4248	SAN No. 2932. Guidance for the Implementation of Section 112(g)—Modifications	2060-AD06
4249	SAN No. 2926. NESHAP: Stage I Gasoline Distribution Facilities	2060-AD93
4250	SAN No. 3168. NESHAP: Petroleum Refining - Other Sources Not Distinctly Listed	2060-AD94
4251	SAN No. 2945. NESHAP: Polymers and Resins, Group II	2060-AD97
4252	SAN No. 2948. NESHAP: Magnetic Tape Manufacturing Operations	2060-AD99
4253	SAN No. 3075. NESHAP: Aerospace Industry	2060-AE02
4254	SAN No. 3193. NESHAP: Secondary Lead Smelting	2060-AE04
4255	SAN No. 3341. NESHAP—Cyanide Chemical Manufacturing	2060-AE45
4256	SAN No. 3192. Permits for Early Reductions Sources	2060-AF10
4257	SAN No. 3048. Decision on the Petition to Remove Caprolactam from the List of H Hazardous Air Pollutants	2060-AF33
4258	SAN No. 2937. Field Citation Program	2060-AD82
4259	SAN No. 3104. Standards for Tank Vessel Loading Operations	2060-AD02
4260	SAN No. 3029. Control Technology Guidelines (CTG)	2060-AD05
4261	On-Board Diagnostics: Revision to Requirements for Storage of Engine Conditions Associated with Extinguishing a Malfunction Indicator Light	2060-AF20
4262	SAN No. 2685. Amendments to Regulations Governing the Importation of Nonconforming Vehicles	2060-AC58
4263	SAN No. 3067. Nonconformance Penalties for 1998 Model Year Emission Standards for Heavy-Duty Engines and Vehicles	2060-AE07
4264	SAN No. 2637. Alternative Test Procedure for the Voluntary Aftermarket Part Certification Program	2060-AC50
4265	SAN No. 2940. Regulations Governing Prior Notice of Citizen Suits Brought Under Section 304 of the Clean Air Act	2060-AD80

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## Clean Air Act (CAA)—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
4266	SAN No. 3571. Acid Rain Program: Revised Group 1, Phase II, NOx Emission Limitations .....	2060-AF44
4267	SAN No. 3575. NOx Emission Limitations for Group 2 Boilers .....	2060-AF48
4268	SAN No. 3348. Protection of Stratospheric Ozone: Labeling; Supplemental Rule .....	2060-AE51
4269	SAN No. 2690. User Fees for Radon Proficiency Programs .....	2060-AC66
4270	SAN No. 2240. Treatment, Storage, and Disposal Facility - RCRA Air Emission Standards .....	2060-AB94
4271	SAN No. 3603. User Fees for Radon Proficiency Programs Rule - Amendment .....	2060-AF40



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

ATTACHMENT

MAY 31 1994

OFFICE OF  
THE ADMINISTRATORMEMORANDUM

SUBJECT: "Science and Judgment in Risk Assessment",  
A Report by the National Research Council (NRC)

FROM: Robert M. Sussman, Chair  
Science Policy Council

Lynn R. Goldman, Vice-Chair  
Science Policy Council

TO: Carol Browner  
Administrator

As you requested, the Science Policy Council (SPC) has reviewed the subject report. This memorandum transmits our analysis and proposed EPA response (Attachment).

In accord with Section 112(o) of the Clean Air Act Amendments (CAAA) of 1990, NRC evaluated the methods used by EPA to assess the risks posed by exposure to hazardous air pollutants. The study was intended to guide the further development of risk-assessment methods to be used in the residual risk provisions of the Title III of the CAAA. However, as a consequence of the wide applicability of the risk-assessment paradigm adopted by EPA and other agencies in the wake of NRC's seminal 1983 report on risk assessment, most of the findings and recommendations have relevance throughout EPA and across the Executive Branch.

As characterized in its accompanying NRC press release, the report offers a two-part message: "... EPA's overall approach to assessing risks is fundamentally sound despite often-heard criticisms, but the agency must more clearly establish the scientific and policy basis for its risk assessments and better describe the uncertainties in its estimates of risk." To that end, the report includes 70 specific recommendations whereby EPA might improve its policies, practices, and methods for risk assessment. The recommendations cover a wide variety of objectives from near-term methodological refinements to long-term research.

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The SPC agrees with the general course of action that NRC advocates. In particular, we view the 73 recommendations, taken together, as providing a sound conceptual framework for our continuing efforts to upgrade health-risk assessments (i.e., both cancer and non-cancer hazards), strengthen the linkages between risk assessment and risk-management, and improve the ways EPA communicates about risk with all interested parties.

The SPC has identified eight thematic areas within which to begin implementing NRC's recommendations. For example, we propose to improve the quality of risk characterizations throughout EPA and make them more prominent in the rule-development process during the coming year. Also, looking further into the future, we propose a special initiative to advance the science of exposure assessment - especially as it relates to dealing with multi-path, multi-source exposure scenarios and cumulative risks, such as those experienced disproportionately by many minority populations and other disadvantaged groups. The Attachment provides a detailed description of our envisioned actions in all eight thematic areas.

In view of the broad scope and inherent complexity of the NRC recommendations, the steps we envision necessarily are only the beginning. A comprehensive response will require a sustained resource-intensive effort for the foreseeable future. The SPC and its Steering Committee plan to update the Attachment from time to time based on our progress, new developments in relevant science and technology, and advice from the Science Advisory Board and others within the many communities of interest outside EPA. Further, we are prepared to work with you and the Senior Leadership Council to integrate the basic themes of the NRC report and the EPA response into the Agency-wide processes for strategic planning and budgeting.

The SPC believes that the combination of the NRC report and our proposed response constitute a realistic, multifaceted approach to improving both our capability for health-risk assessment and its applications in support of environmental protection. We look forward to your comments and guidance as we embark upon the next phase.

#### Attachment

cc: Assistant Administrators  
Regional Administrators  
Members of the Science Policy Council  
Members of the Science Policy Council Steering Committee  
Michael Vandenbergh  
Sylvia Lowrance  
Dana Minerva  
Richard Parker

REPORT OF THE EPA SCIENCE POLICY COUNCIL  
ON ADDRESSING  
"SCIENCE AND JUDGMENT IN RISK ASSESSMENT",  
A REPORT BY THE NATIONAL RESEARCH COUNCIL

BACKGROUND

Pursuant to Section 112(o) of the Clean Air Act Amendments of 1990 (CAAA), the National Research Council (NRC) prepared a report to Congress evaluating the methods used by EPA to assess the risks posed by exposure to hazardous air pollutants (HAPs). The core of the NRC Report focuses necessarily on issues specific to the Office of Air and Radiation (OAR). However, as a consequence of the wide applicability of the risk-assessment paradigm adopted by EPA and other agencies in the wake of an earlier NRC report<sup>1</sup>, most of the findings and recommendations have relevance throughout EPA and across the Executive Branch.

The NRC report contains a comprehensive analysis of the state of the science of cancer-risk assessment and its uses in relation to decision-making at EPA. Risk assessment related to other health hazards is discussed only briefly, and ecological risks are not treated explicitly because they are outside the statutorily defined scope. Nevertheless, many of the concepts discussed in relation to cancer also are germane to non-cancer risks; and several of the fundamental principles apply to ecological risks as well.

As characterized in its accompanying NRC press release, the report offers a two-part message: "... EPA's overall approach to assessing risks is fundamentally sound despite often-heard criticisms, but the agency must more clearly establish the scientific and policy basis for its risk assessments and better describe the uncertainties in its estimates of risk." To that end, the report includes 70 specific recommendations whereby EPA might improve its policies, practices, and methods for risk assessment. Nothing in the report, however, militates for wholesale replacement of the current paradigm.

The recommendations cover a wide variety of objectives from near-term methodological refinements to long-term research. Although some of the recommendations can be implemented in the short term, a comprehensive response will require a sustained resource-intensive effort for the foreseeable future. The Science Policy Council (SPC) views them as a sound basis for upgrading health-risk assessments in general (i.e., both cancer and non-cancer hazards), strengthening the linkages between risk

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<sup>1</sup>National Research Council. 1983. Risk Assessment in the Federal Government: Managing the Process. National Academy Press, Washington, D.C.

assessment and policy-making, and improving the ways EPA communicates about risk with all interested parties.

Of special note is the fact that many of the issues raised by NRC are relevant to the issue of environmental justice. For example, NRC highlights the need to consider the variability in both exposure and susceptibility to chemicals when conducting a risk assessment. This supports the need to consider potentially high-risk subgroups. In addition, the report points out that certain populations may be exposed to multiple chemicals and that risk assessments should consider the "aggregation" or cumulative risks associated with these exposures whenever practical.

SPC identified eight thematic areas within which to begin implementing NRC's recommendations:

- Risk Assessments for Hazardous Air Pollutants
- Risk Characterization
- Integrated Risk Information System
- Cancer Risk Assessment Guidelines
- Assessment of Non-Cancer Risks
- Multi-Path and Multi-Source Exposure Assessment
- Susceptibility to Chemicals: Inter-Individual Differences
- Research to Improve Risk Assessment Tools

These themes and the Agency's initial actions to address them are summarized below.

#### THEMES AND PROPOSED ACTIONS

##### 1. Risk Assessments for Hazardous Air Pollutants (HAPs)

###### Background

Title III of the Clean Air Act Amendments of 1990 requires that between 1998-2006 EPA set residual-risk standards for HAPs that protect public health with an ample margin of safety if it concludes that the technology-based standards have not done so. To accomplish this, EPA must evaluate the level of risk that remains after the application of best available technology to HAPs emission sources. The NRC study was intended to guide the further development of risk-assessment methods to be used in this stage of the regulation of HAPs emissions from point sources.

The NRC report called for EPA to: 1) obtain key data for assessing risks from HAPs; 2) update methods for determining carcinogenic risks associated with HAPs; and 3) improve risk assessment methods for noncancer risks from HAPs. As a first step in implementing NRC's recommendations, EPA's Office of Air and Radiation will accord high priority to acquiring toxicity data on HAPs and improving methods for air toxics exposure modeling.

Objectives and tasks listed directly below describe activities focussed on HAPs. The seven themes discussed in this report are oriented towards improving risk assessment generally throughout the Agency and are also linked to recommendations from the NRC for improving assessments of HAPs.

**Objective 1: Acquire toxicity data on HAPs**

**Initial Task:** Complete proposals for acquiring additional data on HAPs.

**Responsibility:** Office of Air and Radiation; Office of Research and Development; Office of Prevention, Pesticides and Toxic Substances

**Target date:** Summer 1994

**Comment:** More and better data on HAPs would be of value to other EPA programs as well. For example, all HAPs are listed as hazardous substances under Superfund; many are of concern to the Office of Water; and many are subject to reporting under the Toxics Release Inventory.

**Objective 2: Improve air toxics exposure modeling**

Improve capabilities for modeling air-toxics exposures, including use of emissions inventory and exposure data, validating model evaluations against field measurements, and incorporation of uncertainty quantification in a consistent manner.

**Initial Task:** Update modeling section of air toxics issue plan for research, including estimate of resource requirements.

**Responsibility:** Office of Research and Development; Office of Air and Radiation

**Target date:** Fall 1994

**Comment:** Improved modeling for exposures to air toxics could benefit other EPA programs that deal with air-borne hazards, particularly as the Agency moves towards multi-path exposure assessment as an EPA-wide practice, (See also "Multi-path, Multi-Source Exposure Assessment").

**2. Risk Characterisation**

**Background**

The NRC report emphasizes the importance of risk characterization. In general, the comments reinforce current EPA policies in these areas while recognizing that EPA practices need

to be improved. The effort here will be to initiate specific actions to bring practices more closely into line with the Agency's stated policies<sup>2</sup> including:

- Use of Default assumptions
- Inclusion of Qualitative Uncertainty Analysis
- Application of Quantitative Uncertainty Analysis

**Objective 1: Create a mechanism for evaluating EPA's progress**

**Task 1: Design oversight mechanism.**

**Responsibility:** Group designated by SPC Steering Committee

**Target date:** July 1994

**Task 2: Implement oversight mechanism.**

**Responsibility:** Group designated by SPC Steering Committee; periodic review by SPC

**Target date:** Begin implementation August 1994. Report to Administrator no later than one year after implementation.

**Objective 2: Create models of good risk characterizations for different kinds of rules and actions and identify institutional or resource barriers by working closely with several Headquarter offices and regions on a select number of rules or major assessments.**

**Task 1: Develop schedules and processes.**

**Responsibility:** Coordination/resource group to be designated by SPC Steering Committee

**Target date:** July 1994

**Task 2: Work with programs and regions to identify suitable candidates representing different kinds of rules and actions.**

**Responsibility:** SPC Steering Committee and program offices

**Target date:** July 1994

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<sup>2</sup>"Guidance on Risk Characterization for Risk Managers and Risk Assessors". Memorandum from the EPA Deputy Administrator to Agency Regional Administrators and Assistant Administrators. February 26, 1992.

**Task 3: Report on status of model development to SPC Steering Committee.**

**Responsibility: Coordination/resource group to be designated by SPC Steering Committee**

**Target date: September 1994**

### **3. Integrated Risk Information System (IRIS)**

#### **Background**

IRIS is a public data base that holds the consensus findings of EPA scientists on human-health hazard and dose-response characteristics of several hundred chemicals and mixtures. IRIS originally was a resource strictly for internal EPA use but now is available publicly, including on-line access through the National Library of Medicine and international distribution through the World Health Organization. In many respects, IRIS is the public face of EPA risk assessment.

The NRC Report contains many recommendations that affect IRIS including several that mirror the suggestions of EPA's IRIS Quality Action Team. In recent years, the EPA investment in the maintenance and improvement of IRIS (especially support of the two interdisciplinary teams of EPA scientists who develop the information it contains) has not kept pace with the needs of users within EPA and elsewhere. Over the past two years, EPA has mounted an effort (through the activities of a quality action team) to examine mechanisms to gain more peer review and public involvement in the IRIS process.

SPC proposes that its Steering Committee and the Office of Research and Development (ORD) create a multi-year plan to put IRIS on a sound basis. This will involve establishing priorities for data-base development, quality control and other operating procedures, budget, and organizational status. These actions seem the most direct way to address NRC's calls for major improvements in such aspects as the descriptive narratives and justifications; the characterizations of data deficiencies, uncertainties and assumptions; and the scope and intensity of the peer review for IRIS entries.

**Objective: Improve IRIS management and data quality**

Develop Agency policy on the use of information in IRIS, agreed-upon management practices, scope, quality assurance methods, and budget.

**Initial Task: Review report from existing IRIS Quality Action Team and decide whether to act on those recommendations and/or to re-energize that cross-Agency effort or another effort to address Agency-wide IRIS issues**

Responsibility: SPC Steering Committee

Target date: July 1994

#### 4. Cancer Risk Assessment Guidelines

##### Background

The NRC Report is generally supportive of the current EPA approach to cancer-risk assessment for those instances when, in the absence of compelling evidence to the contrary, reliance is placed on conservative default assumptions. Examples include the reliance on the results of animal studies in estimating carcinogenicity in humans and the non-threshold assumption for carcinogens. The NRC Report urges that EPA articulate these default assumptions more clearly and define criteria under which these assumptions could be supplanted by specific data or more biologically based approaches.

To a large extent the points elucidated by the NRC are consistent with ongoing efforts to revise the EPA cancer-risk assessment guidelines. Important parts of EPA's guidelines for cancer risk assessment have become out-of-date as a result of recent research advances, especially new insights into the cellular and molecular events involved in carcinogenesis. Revision of the guidelines will address several of the major themes raised by the NRC report, including: default options and reasons for departing from them in particular instances, variations within human populations with respect to both exposures and susceptibilities to toxic substances, and cumulative effects of environmental hazards.

Revision of the guidelines is underway by the Cancer Oversight Group of the Risk Assessment Forum. In consultation with SPC, ORD has agreed to accelerate this effort to complete a new draft by summer 1994, thereby enabling the Risk Assessment Forum to conduct a public workshop on the draft guidelines later this year.

**Objective:** Complete a new version of the cancer risk assessment guidelines

**Task 1:** Develop a draft of the guidelines that will be ready for Agency review in May, 1994, and hold an external peer involvement workshop in the fall of 1994.

**Responsibility:** Risk Assessment Forum

**Target date:** September 1994

**Task 2:** After the workshop, report to SPC on the issues raised, the process for their resolution, and the overall schedule and resource requirements for completion.

**Responsibility:** Risk Assessment Forum

**Target date:** Fall 1994

### **3. Assessment of Non-Cancer Risks**

#### **Background**

NRC points to the need to develop better quantitative methods for assessing the incidence and likelihood of non-cancer effects in exposed populations. It included discussions of non-cancer risks in its general discussions of variability and uncertainty, models, methods and data, and aggregation of separate but related causes and effects of risk. The EPA Science Advisory Board (SAB) is scheduling a consultation for later this year to discuss the implications of the subject report for non-cancer risk assessment. SPC strongly endorses this consultation and urges that it be accorded high priority. The outcome should provide the basis for developing an expanded program of research and applications with respect to assessing non-cancer health effects.

#### **Objective 1: Develop EPA-wide strategy on non-cancer risk assessment**

Develop an EPA-wide strategy to improve methods for non-cancer risk-assessment and promote their broader application. This strategy would identify whether new or revised Agency guidelines are needed and how and when they could be developed.

**Initial Task:** Two-step consultation with the Science Advisory Board to review the potential implications of the NRC report for the Agency's assessment of non-cancer risks. The consultation will build upon ongoing work related to neurotoxicity, developmental toxicity, and other non-cancer effects and could facilitate efforts to reduce risks from pesticides in the diets of infants and children.

**Responsibility:** Office of Research and Development

**Target date:** first consultation, spring 1994

#### **Objective 2: Assess the utility of the benchmark dose**

The benchmark dose concept has been developed as an alternative methodology for deriving quantitative estimates of hazard, which can be used for both cancer and non-cancer endpoints of toxicity. EPA will analyze what is required to implement the benchmark dose approach (implications on assessments per chemical,

potential effects on risk management decisions, and resources required).

**Initial Task:** Develop both reference standard doses (RfDs) and benchmark doses for next year wherever there are suitable data. This report would be followed by an evaluation to assess general implementation issues associated with adoption of benchmark dose approach.

**Responsibility:** SPC Steering Committee and RfD Workgroup

**Target date:** Summer, 1994

## **6. Multi-Path and Multi-Source Exposure Assessment**

### **Background**

The EPA has not employed multi-path/multi-source exposure assessment routinely in all programs. The NRC Report recommends that EPA consider exposure to air toxics through indirect pathways (such as food sources) and from other air sources (such as mobile and indoor sources) as well as from outdoor stationary sources. SPC concurs in the NRC recommendation not only as it applies to the air-toxics program but also as it affects most other EPA programs. Similarly, the NRC Study on Pesticides in the Diets of Infants and Children recommended consideration of multiple routes of exposure (e.g., dietary and non-dietary) in the evaluation of pesticide risks. Therefore, SPC proposes to initiate the development of an EPA-wide policy on this issue so as to promote systematic consideration of multiple paths and multiple sources of exposure wherever appropriate in the course of risk assessment.

Improving exposure assessment in these areas will address environmental justice concerns by helping to identify subgroups of the population which are highly exposed. More use of multi-path exposure assessment could improve the quality and utility of risk assessments in general as well as accelerate the emergence of multi-media and industrial-sector-specific approaches to protecting humans and the environment

### **Objective 1: Develop an EPA policy on multi-path and multi-source exposure assessment**

Develop an Agency-wide policy directing programs to look at multiple routes of exposure in exposure analyses. The policy will address how to use screening techniques and sensitivity analyses, as advocated by the NRC, to focus such assessments on those pathways which are likely to present the most significant risk.

**Task 1:** Review the report of the existing Agency-wide Relative Source Contribution Task Force, which is developing a consistent Agency approach to issues such as pesticide exposure via drinking water sources.

**Responsibility:** SPC Steering Committee

**Target date:** Spring, 1994

**Task 2:** Monitor experience of the Office of Pesticide Programs as they begin to assess multiple routes of exposure to pesticides. Identify issues of Agency-wide concern.

**Responsibility:** SPC Steering Committee

**Target date:** Fall, 1994

**Objective 2:** Improve methodologies for assessing exposures via multiple pathways and from multiple sources

Wider use of multi-source and multi-path exposure assessment will depend on the availability of appropriate methodologies and supporting data. EPA needs to expand current exposure assessment efforts, especially in the area of fate and transport modelling to trace indirect routes of exposure.

**Initial Task:** Review the current research plan on human exposure and other efforts ongoing in the Agency, and evaluate current priorities in light of the NRC recommendations.

**Responsibility:** Office of Research and Development and Program Offices

**Target date:** Summer 1994

## **7. Susceptibility to Chemicals: Inter-Individual Differences**

### **Background**

The NRC Report recommends that EPA give more emphasis to the issue of human variation in sensitivity to environmental pollutants. This has both policy and research implications. The recommendation builds on and extends the recommendations in the NRC report on "Pesticides in the Diets of Infants and Children" published last year.

The Office of Research and Development and the Office of Prevention, Pesticides and Toxic Substances will summarize the current state of knowledge about human variability in sensitivity to different kinds of chemical pollutants. This paper will be developed in conjunction with ongoing efforts to respond to that

Report and will contain recommendations for additional Federal research and short-term policy options for addressing individual variability in EPA risk assessments.

**Objective:** Develop EPA-wide approach to inter-individual variation in susceptibility

Develop a policy statement and implementation strategy to help risk assessors and risk managers accord appropriate attention to inter-individual differences in susceptibility to toxic chemicals.

Increased attention to inter-individual differences in susceptibility to toxic chemicals could facilitate progress toward several of the Administrator's high-priority goals such as promoting environmental justice and reducing risks from pesticides in the diets of infants and children.

**Task 1:** Participate in effort to plan research strategies across the federal government through the process established by the National Science and Technology Council (NSTC), Committee on Environmental and Natural Resources, and prepare a position paper summarizing the current state of knowledge and the major research needs in this area.

**Responsibility:** Office of Health and Environmental Assessment/Office of Research and Development; Office of Prevention, Pesticides and Toxic Substances

**Target date:** Fall 1994

**Task 2:** Identify policy issues and options for risk assessors and managers, based on current state of knowledge. Effort should coordinate with Agency's response to NRC Study on Pesticides in the Diet of Infants and Children in the areas of toxicology; multi-pathway exposures through consumption of food and water; assessment of pesticide tolerances; and risk assessment methods.

**Responsibility:** SPC Steering Committee

**Target date:** Winter 1994

## 8. Research to Improve Risk Assessment Tools

### Background

The NRC Report recommends that EPA augment existing research with a more broadly-based effort to improve risk-assessment methodologies. The NRC report acknowledges that the responsibility for conducting such risk-related research does not

lie exclusively with EPA but rather is also the responsibility of several other agencies with environmental and public-health responsibilities (e.g., the National Institute of Environmental Health Sciences and the Centers for Disease Control and Prevention).

SPC recommends that, in responding to NRC's call for more research related to improving risk assessment, EPA should maintain its existing research program in many of the areas that are highlighted in the NRC report, including the examination of developmental and reproductive toxicity and pharmacokinetics and metabolism. SPC also recommends that EPA seek to integrate its research with that of other agencies - both directly and through the Committee on Environmental and Natural Resources under the National Science and Technology Council.

**Objective 1: Coordinate research needs through the NSTC**

Highlight needs and opportunities for risk assessment research for consideration by the NSTC as it sets interagency research priorities relative to the environment and natural resources, food safety and nutrition, and fundamental science.

**Initial Task:** Contribute ideas about risk assessment research to the research planning efforts being conducted by the committees of the NSTC.

**Responsibility:** EPA representatives to NSTC Committees

**Target date:** Spring 1994

**Objective 2: Reexamine EPA research priorities for risk assessment research in light of the NRC report**

**Task 1:** Review by Science Advisory Board of the risk assessment research plan.

**Responsibility:** Office of Research and Development; staff directorate, Science Advisory Board

**Target date:** Summer 1994

**Task 2:** Report results of review to SPC.

**Responsibility:** Office of Research and Development

**Target date:** Fall 1994

- 7. Are the requirements of section 3105 for risk characterization (taking into account the definitions in 3106) consistent with the Agency's understanding of sound scientific principles for risk assessment and risk characterization? Would the requirements of section 3105 preclude the Agency from considering any information, models, or assumptions in assessing or characterizing risk? How would the Agency be able to take into account risks to special subpopulations which may have higher susceptibility than "average"?**

The descriptions and definitions of risk characterization discussed in Sections 3105 through 3107 are not consistent with either the National Academy of Sciences (NAS) or EPA's views on risk characterization. Risk characterization is the final step in the risk assessment process described by the NAS and adopted by the Agency. It is much more than the numerical presentation of risks as the Act would suggest. Risk characterization includes a summary of the information in preceding steps, focusing on a discussion of the strengths and weaknesses of the underlying scientific information, a clear statement of the assumptions and uncertainties contained in the assessment, and a qualitative and/or quantitative description of risk.

In the case of cancer risk assessments, the characterization generally includes a quantitative estimate of the upper bound incremental risk for individuals and populations who might be potentially exposed. For non-cancer endpoints, numerical estimates are presented as reference concentrations (levels below which adverse effects are not likely to be experienced). The Agency cannot be more precise about either of these quantitative metrics, despite the Act's apparent requirement for "best" estimates of risk.

The Act's definition of "best" estimates of risk leads to a description of average or mid-range estimates of risk as if they were "most plausible" and "unbiased." In reality, this central estimate of risk is often more uncertain than bounding estimates. For both statistical and biological reasons, "best" estimates are highly unstable when calculated from typical data sets. Since all models used for calculating risks are inherently biased, the requirement to use "unbiased" models might, in essence, preclude quantitative characterizations under a literal interpretation of the Act.

Use of other than "most plausible" assumptions seem to be accorded less weight under the Act. However, "most plausible" estimates do not adequately characterize subpopulations in terms of either exposure or sensitivity. Estimations of sensitive subpopulations may be required under existing legislation and would be of primary importance in risk management decisions under FIFRA and the Clean Air Act.

The national air quality standard-setting programs by law must consider special populations that may be especially vulnerable to air pollution, such as asthmatics. The requirements for risk characterization in Section 3105 may conflict with this legal requirement.

8. To the extent not already addressed in previous answers, please identify all risk assessment documents, regulatory proposals or decisions, reports to Congress, or other documents made available to the public by the Agency, which include characterizations of risks that would be subject to the requirements of section 3105.

Risk assessments underlie many of the thousands of regulatory decisions made by EPA programs, and with the exception of certain emergency actions, an argument may be made that all of these risk assessments would be subject to section 3105. There have been a number of extremely useful documents produced by EPA over the last several years that might have been subject to the requirements of section 3105, and, as a result, could have been significantly delayed in their development and publication. Some examples include:

- **EPA's 1991 Advisory to the Public on Asbestos in Buildings:** EPA issued this advisory, which characterized the current knowledge of asbestos risks, to set the record straight in light of a spate of confusing and misleading scientific and news reports. In this report, EPA encouraged management of asbestos in-place, wherever possible.
- **"Lead and Your Children" brochure (1992):** characterized the risks to children from lead exposure and some simple steps for parents to take to avoid childhood lead poisoning. This brochure has been widely praised by local groups and states.
- **"Reducing Lead Hazards When Remodeling Your Home" brochure (1994):** purpose is to help reduce lead exposure when conducting home renovation and remodeling activities and to provide information about lead hazards. This pamphlet provides the home owner with basic information that could reduce the exposure of risk to their children.
- **Lead Hazard Information Pamphlet (proposed 1994):** required by The Residential Lead-Based Paint Hazard Reduction Act of 1992, contains information regarding the health risks associated with exposure to lead and, in particular, describes the risks of lead exposure for children under 6 years of age, pregnant women and others residing in a dwelling with lead-based paint hazards.
- **Data Evaluation Reports (DERs) --** Every year, EPA reviews over 10,000 studies for purposes of registration, tolerance setting, re-registration, and other regulatory actions. Each of these reviews is written down in a data evaluation report, and the vast majority arguably are subject to H.R. 9.
- **Science Chapters --** EPA produces approximately 40 Reregistration Eligibility

Decisions annually which are based on "Science Chapters" which summarize and integrate the DERs for a particular chemical in one of several scientific disciplines, e.g. environmental fate, residue chemistry, occupational exposure, toxicology, etc.

- **Special Review Position Documents** -- EPA conducts an intensive, participatory process to examine the risks and benefits of pesticides posing significant risks to public health and the environment. In announcing the initiation of this "Special Review" process, and in proposing and finalizing regulatory decisions, EPA presents its analyses of risks and benefits in detailed position documents.
- **The Hazardous Waste Minimization and Combustion Strategy** -- Through enhanced public outreach and dialogue, stringent risk assessment requirements, amendments to technical standards, and permitting and enforcement initiatives, EPA is taking strategic steps to ensure that combustion of hazardous waste is fully protective of human health and the environment.
- **The National Waste Minimization Plan** -- The plan represents EPA's vision with respect to source reduction and environmentally-sound recycling of all wastes. The plan places top minimization compliance priority on facilities driving the demand for waste combustion.
- **Superfund Presumptive Remedy Selection Guidance** -- In support of efforts to streamline the Superfund program and provide consistency at clean-up sites, the guidance contains valuable implementation information on the appropriate selection of technologies (remedies).

Several of these documents are attached for your information.

9. **Please estimate the cost of complying with the peer review requirements of section 3301, taking into account the provisions of Title VII requiring Regulatory Impact Analyses. How would the Agency implement the requirements for peer review of "economic assessments", "economic information" and "cost assessments"? How long would such a process be likely to take?**

The Agency has interpreted H.R. 9 to require peer review for any risk assessments and cost-benefit analyses for actions that cost society more than \$25 million per year. Our response to question 6 on the additional time and resource necessary to carry out several provisions of H.R. 9 answers this question, but for ease of presentation, we repeat the discussion on time below.

**Estimated time to complete peer review.**

Assumptions: We read the Act to require peer review only for rules with impacts in excess of \$25 million. An additional assumption is having the appropriate peer review experts available.

Rough Estimate: An additional **3-6 months** would be necessary to comply with the peer review requirements. This would allow time to convene the peer review panel, have them conduct their review and draft their report to EPA.

Note, to estimate the additional time needed to develop any specific rule, and comply with these new requirements, we would determine the likely dollar impact of the rule to know which of these requirements would apply and sum the incremental times.

Under the peer review requirements of H.R. 9, EPA could need to spend, on an annual basis, an additional \$5 million in personnel costs (equivalent to approximately 62 additional FTEs) and an additional \$16 million in extramural analytical costs. These costs assume that the baseline level of regulatory activity set under statutory deadlines, consent decrees, and other rationale used to develop the Agency's regulatory agenda will not be modified. The baseline level of intramural (FTE) and extramural (analytic) resources now devoted to these is approximately \$4 million and \$5 million per year, respectively. Therefore, the need to increase FTEs would require more than doubling internal staff (about 120% increase over the FTE base) and more than quadrupling extramural resources devoted to peer review (about 360% increase over the analytic base).

Based upon a preliminary analysis of EPA's regulatory agenda, we estimate the additional analytic and personnel costs of conducting additional peer reviews will be the following:

Estimated Annual Costs to EPA to Comply with Peer Review Provisions of H.R. 9, Titles III and VII  
(Costs in Millions of 1995 Dollars)

	<u>INCREMENT FTE \$</u>	<u>INCREMENT ANALYTIC \$</u>	<u>TOTAL INCREMENT \$</u>
RA Peer Review	\$3	\$10	\$13
BC Peer Review	<u>\$2</u>	<u>\$6</u>	<u>\$8</u>
Total	\$5	\$16	\$21

**Would the Agency be precluded from issuing any regulation until the required peer review, peer review report, and response to the peer review, had been completed and made available to the public?**

Subtitle C of Title III is written in mandatory terms. If EPA issued a rule without fully complying with the peer review requirements, the rule could be overturned by a reviewing court.

**Would such peer review panels be subject to the Federal Advisory Committee Act?**

The peer review panels would probably be advisory committees within the meaning of Section 3 of the Federal Advisory Committee Act (FACA), 5 USC app. 2, and therefore have to be chartered. The Administration has committed to limiting the number of Federal Advisory Committees. EPA is currently under tight constraints about the number of committees it can have.

## Attachment to Question 6:

Below are the proposed and final rules projected by EPA from the present date forward for FY 1995-96. This list is based on EPA's entries in the Regulatory Agenda. The list is divided into those requiring a Regulatory Impact Analysis; those requiring a certification under ; and those requiring peer review under .

Note that these numbers are rough projections, that the analyses necessary to support impact calculations have not been completed in many cases, and that major decisions about the content of these actions have not been made in some instances. Lists such as this are very dynamic. These projections will change as the statutes change and as a result of court-orders.

## Regulatory Impact Analysis Requirements under Title VII Rules of \$1 million or greater

### Office of Water

#### Effluent Guidelines:

- Centralized Waste Treatment -- final rule
- Coastal Oil and Gas -- proposed rule
- Metal Products and Finishing -- proposed rule
- Pharmaceuticals -- proposed rule
- Pesticide Formulation Packaging and Repackaging -- final rule
- Pulp and Paper -- final rule

#### Water Quality Standards

- Florida
- California
- New Mexico

#### Revised recreational criteria for micro-organisms

- Guidance establishing testing procedures for analysis of pollutants under Clean Water Act
- NPDES Industrial Permit Application Form -- proposed rule
- NPDES and Sludge Municipal permit application forms and regulatory revisions -- proposed rule
- Continuous emission monitoring regulation and other pollutant limitations; monitoring requirements for sewage sludge -- proposed rule
- Stormwater regulations -- final rule
- Wetlands: Definition of Isolated waters and artificial wetlands -- proposed rule
- Sediments: comparison of dredged material to reference sediment
- Shore protection act regulations -- final rule
- Great Lakes Water Quality Guidance -- final rule
- Ocean Dumping: Revisions to dumping regulations for dredged material -- proposed rule

**National Primary Drinking Water Regulations:**

- Sulfate -- proposed rule
- Radionuclides -- final rule
- Ground water disinfection -- proposed rule
- Arsenic -- proposed rule
- Disinfection By-Products -- final rule

Disinfection By-Products: Information Collection Rule -- final rule

Organic and Inorganic Contaminates (VIB) -- proposed rule

UIC -- Underground Injection Class V -- proposed rule

Underground Injection Class II -- Oil and Gas Wells

**OPPTS**

**See attached matrix for specific rules**

**OSWER**Proposed rules:

Spent Solvents Listing Determination

Chlorinated Aliphatics Listing Determination

Guidelines for Federal Procurement of Paper Containing Recovered Materials

Revisions to the Comprehensive Guideline for Procurement of

Products Containing Recovered Materials

Rule Identifying when Military Munitions Become Hazardous

Wastes and Management Standards for such Wastes

Hazardous Waste Manifest Regulation

Final Rules:

Comprehensive Procurement Guidelines for Products Containing

Recovered Materials

**OAR**

**See attached Regulatory Agenda**

**Analysis of Risk Reduction Benefits and Costs or a Certification under  
Subtitle B of Section 3201 of Title III  
Impacts of \$25 million or greater**

For these rules, regulations would have to include all the requirements under the RIA (>\$1 million or 100 people) PLUS the analysis of risk reduction benefits and cost and a certification under Subtitle B of Title III.

**Office of Water**

**Effluent Guidelines:**

Centralized Waster Treatment -- final rule

Coastal Oil and Gas -- proposed rule

Pharmaceuticals -- proposed rule

Pesticide Formulation Packaging and Repackaging -- final rule

Ocean Dumping: Revisions to dumping regulations for dredged material -- proposed rule

National Primary Drinking Water Regulations:

Sulfate -- proposed rule

Underground Injection Class II -- Oil and Gas Wells

**OPPTS**

**See attached matrix**

**OSWER**

Proposed rules:

Land Disposal Restrictions (LDR) Phase III

Listing Determination of Wastes Generated during  
the Manufacture of AZO, Anthraquinone, and  
Triarylmethane Dyes and Pigments

Revisions to Criteria for Solid Waste Disposal Facilities  
that May Accept CESQG Hazardous Wastes Excluding  
Municipal Solid Waste Landfills

Location Standards for Hazardous Waste Facilities

**OAR**

**See Attached Regulatory Agenda**

Peer Review under Section 3301

Impacts of \$100 million or greater

For these rules, EPA would have to conduct an RIA, a cost-benefit analysis and certification under Title III, and peer review under section 3301.

## **Office of Water**

### **Great Lakes Water Quality Guidance**

#### **Effluent Guidelines:**

Metal products and finishing  
Pulp and paper

NPDES Industrial Permit Application Form -- proposed rule

Inorganic and Organic Contaminates VIB -- proposed rule

National Primary Drinking Water Standards

Radionuclides

Ground water disinfection

Arsenic

Disinfection By-Products

Disinfection By-Products Information Collection Rule

Underground Injection Class V

## **OPPTS**

See attached matrix

## **OSWER**

### Proposed rule:

Hazardous Waste Combustion Revised Technical Standards

Land Disposal Restrictions Phase IV

Listing Determination for Petroleum Refining

Process Wastes

Risk Management Program for Chemical Accident Prevention

### Final Rule:

Corrective Action for Solid Waste Management Units at

Hazardous Waste Management Facilities

Revisions to the Oil Pollution Prevention Regulation

## **OAR**

See Attached Regulatory Agenda -- those with asterisks have an impact of >\$100 million



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

January 27, 1995

The Honorable George E. Brown, Jr.  
Committee on Science  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Brown:

I am pleased to offer, in response to your request of January 20, 1995, the Nuclear Regulatory Commission's (NRC's) responses to the specific questions that you asked regarding Title III and related provisions of H.R. 9, the proposed "Job Creation and Wage Enhancement Act of 1995." These responses are found in Enclosure 1. I am also pleased to provide in Enclosure 2 the NRC's more general, preliminary analysis of the likely effect on NRC activities and programs of Titles III, IV, VII, and VIII of H.R. 9.

The overall objectives of Title III of the proposed law -- a sound evaluation by agencies of the risks at which regulations are directed; a sensible balancing of costs vs. benefits, to ensure that new regulations are justified; and appropriate peer review to ensure the scientific validity of regulatory approaches -- are ones which the Nuclear Regulatory Commission not only endorses, but has already incorporated into its regulatory processes. For example, the NRC more than a decade ago put into effect, for power reactors, the "backfit rule," 10 CFR § 50.109. This rule requires a rigorous analysis before any backfitting (which may be defined loosely as an increase in the stringency of regulation) can take place, unless that increased stringency is needed to fulfill our statutory mandate to provide "adequate protection of public health and safety". The NRC also established a "Committee for the Review of Generic Requirements" as an internal control to ensure that new requirements are justified. Scientific peer review is provided by the Advisory Committee on Reactor Safeguards, an independent advisory committee specifically established by statute as a peer review mechanism, and by other expert advisory committees, including the Advisory Committee on the Medical Uses of Isotopes, and the Advisory Committee on Nuclear Waste. In short, the NRC already has mechanisms in place that we consider extremely effective means of guaranteeing the scientific quality of new regulations, and of ensuring that any new requirements have passed through exacting scrutiny.

The proposed legislation, however, which is directed to government agencies generally, may pose special problems for the Nuclear Regulatory Commission. Some provisions could be interpreted to conflict with the NRC's organic statute, the Atomic Energy Act of 1954. While such interpretations would not appear to be consistent with the intentions of the bill's proponents, you may wish to consider clarifying language to address four issues that reflect the special nature of NRC's statutory obligations.

First, the Atomic Energy Act directs the NRC to adopt regulations that are necessary to assure "adequate protection of public health and safety." This statutory "floor" is required to be established irrespective of the costs involved. Although cost balancing is appropriate where alternative means of achieving the floor are available, the NRC must establish the floor even if all alternatives appear costly. For example, when changes in the rules are sought by NRC's licensees to achieve some economic benefit or improvement in performance, the NRC can legally take into account the cost of compliance if the adequate protection standard is otherwise met. Although the NRC has for many years formally differentiated between these two types of regulations -- to the extent of requiring, through its "backfit" regulation, that any regulations on power reactors over and above "adequate protection" must meet rigid cost-benefit tests -- the proposed legislation does not specifically recognize such a differentiation.

Second, NRC regulation, unlike other regulatory schemes, is integral and essential to permitting the private sector operation and profit from NRC-licensed facilities -- most notably, the nation's more than 100 nuclear power plants. The reasons for this go back to the inception of the nuclear power industry. Originally, nuclear energy was exclusively the province of the Federal Government, for military purposes. In the Atomic Energy Act of 1954, Congress determined that this novel and potentially dangerous technology should be adapted to civilian uses, for the generation of electricity. It did so in the recognition, which has never been challenged by the regulated industry or anyone else, that extremely close supervision by the Federal Government was and would remain indispensable. For this reason, it is difficult to assess the overall "costs" of NRC regulation in any meaningful sense. The NRC role, at least with respect to nuclear power plants, may be contrasted with regulation of industries -- mining, for example -- which antedate federal regulation. In this regard, the provision for OMB approval of new regulations could also prove to be inconsistent with NRC's distinctive role as a regulatory agency responsible for exercising independent safety expertise.

Third, the NRC is required by statute to recover approximately 100% of its operating costs from its licensees. The proposed legislation, apparently in order to minimize intrusion on the private sector, requires agencies to comply with a host of procedural requirements which would increase NRC costs. Since these increased costs would be passed on to our licensees, the unintended effect of the legislation could well be to increase rather than decrease the burden on the regulated industry.

Finally, in view of the NRC's statutory mission, under the Atomic Energy Act, to ensure adequate protection of the health and safety of the public, and to conduct whatever inspections may be needed to fulfill that mission, the proposed legislation's Miranda-type warnings and rights have the potential to hamper the agency seriously in doing its job of protecting the public. For example, NRC has resident inspectors, who deal with the NRC's power reactor licensees continuously -- and indeed, are available on a round-the-clock basis. From the inception of the nuclear power industry, the basis of the relationship between the NRC and its licensees has been one of constant communication. These provisions of the legislation, on the other hand, seem

likely to impede communication, to foster a more adversarial rather than a more cooperative relationship, and by diminishing the effectiveness of the regulatory program, to undermine public confidence in the regulated industry and its regulators.

In sum, the proposed legislation, could have unintended effects that could undermine the regulated industry; increase the cost to industry of NRC regulation; and diminish public confidence in the safety of the industry. For these reasons, and as discussed in the attachment, we suggest that if the legislation goes forward, it should include a provision to ensure that the Commission's obligations under the Atomic Energy Act are not compromised. For example, the legislation might allow the NRC to waive compliance with any portion of the statute that in the view of the Commission would conflict with the NRC's obligations under the Atomic Energy Act. Any such determination by the Commission, and the Commission's rationale, would have to be communicated to the Congress, which would have the power to override it.

Sincerely,



Ivan Selin

Enclosures:

1. Response to Questions
2. Preliminary Comments on  
Selected Titles of H.R. 9

cc: Representative Robert S. Walker

QUESTION 1.

Please identify the programs in the Commission which would be subject to the requirements of the Risk Assessment and Communication Act of 1995 (Title III of H.R. 9), taking into account Title VII and other relevant sections of H.R. 9.

ANSWER:

- The NRC programs that would be affected by this legislation include all NRC initiatives involving safety enhancements for reactor and materials licensees.

The NRC's central overriding mission, as required under the Atomic Energy Act, is to ensure adequate protection of the health and safety of the public. In this context, it considers a broad range of regulatory and licensing actions necessary to meet adequate protection, compliance with existing regulation, and the initiation of new requirements to enhance public health and safety. It is only when additional safety requirements are contemplated over and above what is necessary to meet the adequate protection standard, that the NRC can legally take into account the cost of such incremental requirements.

However, depending on its interpretation, the law may also establish a number of requirements on the various risk assessments which the agency conducts in order to carry out its licensing functions. This would include the environmental assessments, environmental impact statements, and safety evaluation reports

QUESTION 1. (Continued)

- 2 -

which are developed in support of the regulatory decisions which the agency makes each year related to specific reactor and materials licensees.

QUESTION 2. Using the definitions of "risk assessment" and "risk characterizations" set out in section 3107 of the Act, how many risk assessments and risk characterizations were prepared by, or on behalf of, the programs in the Commission over the last fiscal year? Of those, how many would be considered to be a "screening analysis" exempted under Section 3103(b)(2)?

ANSWER:

- A total of 29 regulatory products were prepared over the past fiscal year that involved significant risk assessment / risk characterization. The NRC issued six rules, prepared seven regulatory guides, issued three +bulletins, published five generic letters, and prioritized/resolved eight generic safety issues over the period covering approximately the fiscal year 1994. The attachment shows in more detail the subject areas covered by these products. However, depending upon interpretation, hundreds of other regulatory products may be covered by the Bill as explained below.

The regulatory products identified are not screening analyses (Sec. 3103,(b)(2)(B)) because restrictions on activities could have resulted from them. However, NRC uses risk assessments in screening analyses to determine whether threshold criteria are met that may justify development of significant regulatory products. Such analyses are subject to the exception under Sec. 3103, (b)(2)(A) as noted below.

QUESTION 2. (Continued)

- 2 -

The NRC uses probabilistic techniques on a daily basis to assist in the evaluation of incidents and other experience reported from commercial nuclear power plants. These evaluations include either a qualitative or quantitative "screening analysis" for the purpose of assessing the significance of the event with respect to risk. The results of these evaluations are used as a guide in determining if a more in-depth follow-up investigation (i.e technical review or inspection) is appropriate and the priority it should have. Qualitative screening analyses involve a comparison of the facts surrounding the event with insights regarding risk which have been obtained from a Probabilistic Risk Assessment (PRA) conducted for the plant involved or with generic insights obtained from the collection of PRAs conducted for plants of similar design. Quantitative screening analyses employ logic models to quantify the potential that existed for a more serious event if plant systems and/or personnel had responded differently during the actual event. The NRC staff estimates that on average, it screens about 2 incidents per day with probabilistic techniques.

In addition to risk assessments and characterizations prepared in support of generic activities such as rulemakings and guidance development, the provisions in section 3103 and 3107 (unlike section 3201, which is limited to major rulemakings) may be applicable to environmental assessments, environmental impact statements, and safety evaluation reports conducted by NRC in support of specific licensing

QUESTION 2. (Continued)

- 3 -

actions. This could have a significant impact on NRC licensing activities. For example, in the Low-Level Waste and Decommissioning area, approximately 50 risk assessments and risk characterizations which would fall under section 3107 were developed during Fiscal Year 1994. These documents were prepared in support of licensing actions in the low-level waste and decommissioning program areas, as well as in support of radiological assessments related to unlicensed or formerly licensed activities. Very few if any of these assessments and characterizations would be exempted as "screening analyses" under section 3103(b)(2).

QUESTION 3. Please describe the Commission's present practices, including references to any published guidelines or procedures, relating to risk assessment, risk characterization, cost-benefit analysis, or peer review.

ANSWER:

- Enclosed is a summary of current uses of risk analysis at NRC (enclosed).

The NRC fulfills its mission of protection of the public health and safety by limiting exposure to ionizing radiation and makes its regulatory decisions on the acceptability of radiation dose based upon risk. Recommendations for dose limits for members of the general public and radiation workers are provided by the International Commission on Radiological Protection (ICRP) and, for the United States, by the National Council on Radiation Protection and Measurements (NCRP). The ICRP and NCRP perform risk assessments for effects of exposure to radiation based upon animal research and studies of radiation effects on humans. The 1977 ICRP-recommended dose limits have been adopted by NRC and reflect ICRP recommendations for acceptable risk selections for radiation workers and the public. EPA has proposed revisions to the Federal Radiation Protection Guidance for protection of the general public that will conform to the 1977 ICRP recommendations. NRC regulates its licensees on a site-by-site basis under the "umbrella" of these upper-bound dose limits and then applies measures to reduce doses to as low as reasonably achievable. Thus, the fundamental basis for

QUESTION 3. (Continued)

- 2 -

NRC's regulatory program to protect the public health and safety is risk-based decisionmaking.

The NRC is also providing a copy of the current draft of the NRC-EPA White Paper on Risk Harmonization (enclosure 2), which primarily focuses on risk assessments for the materials program. In its present form, this White Paper provides concise summaries of many of the factors that NRC would be required to address under this proposed legislation.

The NRC has performed cost-benefit analyses since the inception of the NRC. The NRC issued "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, January 1983, which lays out NRC's underlying policy regarding such analyses. Further, in December 1983, the NRC issued "A Handbook for Value-Impact Assessment," NUREG/CR-3568. These documents, the Guidelines and the Handbook, are the principal guidance documents presently relied upon concerning the development of NRC cost benefit analyses. However, the NRC is currently in the process of revising these documents. Proposed revisions were published in draft form (Guidelines, NUREG/BR-0058, Rev. 2, August 1993, and "Regulatory Analysis Technical Evaluation Handbook, NUREG/BR-0184, August, 1993). The proposed Guidelines were peer reviewed by the Advisory Committee on Reactor Safeguards, an independent advisory committee established by statute, and were also subject to public comment.

QUESTION 3. (Continued)

- 3 -

The proposed revision to the Guidelines reflects 1) the NRC's accumulated experience with implementing the previous Guidelines; 2) changes in NRC regulations and procedures since 1984, especially the Backfit Rule and Policy Statement on Safety Goals for the Operation of Nuclear Power Plants; 3) advances and refinements in regulatory analysis techniques; 4) regulatory guidance for Federal agencies issued by the Administrative Conference of the United States and the Office of Management and Budget; and 5) procedural changes designed to enhance NRC's regulatory effectiveness. The new Handbook expands upon the policy concepts included in the new Guidelines, and provides a full array of implementable methodologies and standard methods for the preparation and presentation of regulatory analyses. Final Guidelines and a Handbook are expected to be issued in 1995.

QUESTION 3. (Continued)

- 4 -

Background/Additional Information.

## ENCLOSURE TO QUESTION 3

## SUMMARY OF CURRENT USES OF RISK ANALYSES AT THE NUCLEAR REGULATORY COMMISSION

## A. Licensing of Reactors

Licensing Reviews of Advanced Reactors: Under the provisions of 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," the NRC staff is currently reviewing submittals from several reactor vendors on advanced reactor designs, as part of a certification process for these designs.

Part 52 requires that a Probabilistic Risk Assessment (PRA) be submitted as part of the application for design certification. However, it does not include specific guidance as to how the PRA should be used. The staff uses of the PRA now include characterizing the design risk profile for the reactors under review, including identification of design strengths and weaknesses, the degree of tolerance to human errors, and the capability to withstand severe accidents.

Plant-Specific Licensing Actions: Licensing actions, including license issuance, amendments, waivers, justifications for continued operation,

**QUESTION 3. (Continued)**

- 5 -

extensions, and revocations, involve technical and regulatory reviews and a determination of adequate safety. The purposes of the program are to ensure that licensing actions keep the plant's design and operation within acceptable risk and that compliance with regulations is maintained so that the health and safety of the public are protected.

The NRC's current practice is to base licensing decisions on deterministic evaluations of compliance with the plant licensing basis as documented in the docket files. PRA has been used primarily to support the decision making process by evaluating the need for immediate action in response to operational experience or in cases where plants are found to be outside the original licensing basis.

**B. Regulation of Reactors**

Monitoring Operation - Inspection: NRC inspections help to ensure that the operation of licensed facilities does not introduce undue risk to the health and safety of the public. This is achieved through the inspection of all safety-related aspects, including the construction, operation, and decommissioning of licensed facilities. The principal measure of inspection findings is in terms of compliance with technical specifications or other applicable regulatory requirements.

QUESTION 3. (Continued)

- 6 -

The objective of PRA use in inspections is to provide risk-based insights as guides for efficient use of limited staff inspection resources. PRAs can provide a relative ranking of safety-related plant systems, components, and operations so that the inspection can be directed at the most risk-significant items at a specific site or generically.

Screening of Operational Events: Certain types of operational events that occur at licensed reactor facilities must be reported to NRC under the provisions of 10 CFR 50.72 or 50.73. The overall purpose of this program is to provide an initial screening of these events for safety significance by considering a number of factors, including significance to core damage frequency. The screening is performed to determine (1) which events merit further review and (2) what aspects of the event are of most significance and should be addressed in additional reviews.

In this screening process, simple PRA models are used to obtain an estimate of conditional reactor core damage probability, given that the event has occurred. This estimate is used as a prioritization measure.

Issue Analyses for Operational Events: If an operational event passes the initial screening above, additional analyses, possibly a more detailed risk analysis, are performed. This program includes more detailed analyses of the screened events and important events that are reported under the provisions of 10 CFR 50.72 and 50.73.

QUESTION 3. (Continued)

- 7 -

The objective of the analysis of operational events is a more detailed understanding of the event and its quantitative "risk" impact as part of an evaluation of possible regulatory action. Such analyses are also used to obtain a "risk index" for the nuclear industry (i.e., a measure of the risk posed by the set of licensed reactors as a function of time).

Operational Data Analyses: Engineering evaluations are made of groups of operational events from Licensee Event Reports (LERs) and from NPRDS (Nuclear Plant Reliability Data System) data on specific components or systems in order to determine failure mechanisms, safety implications, and core damage frequency impacts.

The objective of these analyses are to use PRA to evaluate the effect of the set of events and data on estimates of core damage frequency.

Operational Data Trending: Equipment failures in licensed reactor facilities are monitored by NRC through two data systems, the Nuclear Plant Reliability Data System (NPRDS) and Licensee Event Reports (LER). The staff uses the NPRDS and LER event databases to determine trends in component and system availability or reliability and to identify safety and risk concerns.

In this program, PRA is used to evaluate the impact of a change in a failure rate or failure probability of a component or system on estimated core damage frequency.

QUESTION 3. (Continued)

- 8 -

Generic Safety Issues: A generic safety issue is defined as a possible deficiency in the design, construction, or operation of a class of NRC-licensed installations or activities. The purposes of the generic issue resolution process are to decide whether the issue does indeed represent a significant deficiency, to identify a cost-effective solution, and to implement this solution or set of solutions, if appropriate. Issues studied in this process will have first been screened in an issue prioritization process, as discussed above.

Risk analysis is used to evaluate the potential change in risk associated with resolution of the issue. This analysis must be capable of supporting a decision on whether the potential change in risk is sufficient to justify regulatory action. The analysis also provides the benefit portion of the staff's cost-benefit analysis if it is needed to support regulatory action for enhanced safety. In addition to its quantitative uses, the probabilistic analysis of a generic safety issue provides an important secondary use, in that it serves as a disciplined, uniform, and comprehensive framework that generally forces the staff to define the issue carefully and to consider all aspects, both positive and negative, of its resolution.

Generic safety issues are prioritized so that the maximum benefit will be gained from available resources. For generic issue prioritizations, there are three objectives of the risk analysts.

QUESTION 3. (Continued)

- 9 -

1. To provide a systematic and disciplined framework that forces the analyst to define the issue and its relationship to risk explicitly.
2. To screen out the issues that do not merit further attention because they have no or very little risk significance.
3. To provide a quantitative measure for placing the remaining issues in prioritized categories of importance, thus permitting the most cost-effective use of the agency's resources.

Severe Accident Issue Analyses: The NRC is responsible for planning and executing an extensive research program on the physical processes expected to occur during a severe accident in light water reactors.

In some cases, PRA methods are used in the analysis and resolution of the impact of a physical process or set of physical processes (e.g., in the resolution of BWR Mark I shell failure by direct contact with molten core material).

Facility Analyses: The purpose of a facility analysis is to assess realistically the risk to the public from the operation of an entire nuclear power plant; i.e., the risk from the entire set of initiating events, component failures, human errors, etc., as opposed to the risk from one issue. This analysis may provide a general measure of present plant risks, or it may

QUESTION 3. (Continued)

- 10 -

be done in response to specific regulatory concerns (e.g., to provide an integrated perspective on a new design).

Facility analysis was the original use of probabilistic risk assessment, at least at NRC, beginning with the Reactor Safety Study in 1975. By using probabilistic techniques to estimate the frequencies of various accident scenarios, along with realistic calculations of the consequences of these scenarios, the safety profile of the installation can be analyzed in a systematic, realistic, and integrated manner. In addition, facility PRAs may improve or extend the capabilities of PRA by introducing new methods or updated data.

Individual Plant Examinations (IPEs): The IPE program is a subset of facility analyses. The purposes of the IPE program are to have each commercial nuclear power plant licensee (1) develop an overall appreciation of severe accident behavior, (2) understand the most likely severe accident sequences that could occur at the plant, (3) gain a more quantitative understanding of the overall frequencies of core damage and radioactive releases, and (4) if appropriate reduce the overall frequencies of core damage and radioactive material releases by modifying hardware and procedures that would help prevent or mitigate severe accidents. This program principally focuses on licensee use of IPE/PRA information. However, the information contained in the IPEs is also of potential benefit to the NRC staff in its regulatory programs.

QUESTION 3. (Continued)

- 11 -

When such a submittal is received, the staff review concentrates on the licensee's process (i.e., methods and underlying assumptions). The review is not of a depth and thoroughness to validate the correctness of the results of the licensee's PRAs. Thus, the review of the IPE does not imply that the licensee's PRA is acceptable as a basis for licensing actions (such as modifications to technical specifications). The review focuses on the adequacy of the process in ensuring that the licensee has educated itself in severe accident phenomena, containment response, the principal accident scenarios, and the likelihood of core damage sequences.

Upon completion of the review, findings and rationale for acceptance are documented in a Staff Evaluation Report (SER) and issued back to the licensee. The SER focuses on key areas essential to understanding the IPE findings, their associated strengths and weaknesses, important insights, and any recommendations for follow-on activities. Acceptability of a licensee's IPE process is based on the extent to which the process met the intent of Generic Letter 88-20.

Regulatory Analyses: A regulatory analysis is a structured analyses of all relevant factors associated with the making of a regulatory decision. Many regulatory analyses will fall into the classification of backfit regulatory analyses. Backfitting is defined at 10 CFR 50. 109(a)(1) as "the modification of or addition to systems, structures, components, or design of a facility; or

QUESTION 3. (Continued)

- 12 -

the design approval or manufacturing license for a facility; or the procedure or organization required to design, construct, or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position ...." These backfitting requirements apply only to production and utilization facilities as those terms are defined at 10 CFR 50.2. Similar backfitting requirements apply to independent spent fuel storage facilities (10 CFR 72.62) and to gaseous diffusion plants (10 CFR 76.76).

The objective of a risk analysis is to provide quantitative measures of the "inadequacy" of the situation before imposition of the back fit and the quantitative change in safety the backfit would cause.

Reviews - High-Level Waste Repositories: Performance assessment plays a major role in the NRC's licensing program for the disposal of high-level radioactive waste (HLW). Because the performance assessment of a repository of HLW involves comparing quantitative estimates of repository performance to quantitative performance standards, performance assessment is often the discipline or phase of repository development in which information and knowledge from a variety of technical and scientific disciplines are integrated into a few quantitative measures of performance.

QUESTION 3. (Continued)

- 13 -

The steps in performance assessment include 1) System Description, to describe the various important components of the waste disposal system in terms useful to modeling radionuclide migration to the environment; 2) Scenario Analysis, to postulate and screen a range of potential futures in which the repository must operate, and to estimate the probabilities of individual scenarios; 3) Consequence Analysis, to estimate the performance of the repository for a given scenario by assessing the cumulative release of radionuclides to the environment; 4) Performance Calculation, to combine the estimates of consequences with the corresponding probability of occurrence; 5) Sensitivity and Uncertainty Analyses, to determine through sensitivity analyses which parameters, phenomena, processes, and/or assumptions most greatly influence the estimated value of the performance measure, and through uncertainty analysis, to delineate all the sources of uncertainty, quantify these uncertainties and the uncertainty in the performance estimates, and relate the uncertainty in estimates of performance to the various sources of uncertainty; and 6) Comparison to Regulatory Standard to use judgment to evaluate whether the estimated performance, with its associated uncertainties, satisfies or fails to satisfy regulatory standards, which are limits on performance.

Risk Analyses - Medical Devices: The purpose of this program is to evaluate the use of PRA in developing risk-based regulation of devices with radioisotope sources used in medicine.

Traditional methods used in assessing risk in nuclear reactors may be inappropriate to use in assessing medical radiation risks. Reactor PRAs are

QUESTION 3. (Continued)

- 14 -

machine-oriented with a human failure component associated with critical machine failure events. In assessing the risk of administering an incorrect radiation dose to a patient, the primary source of failures seems to stem from the actions of people and only secondarily from machine failures. This basic difference requires the development of a person-centered approach to risk assessment that will yield relative risk profiles.

Q.3

NUREG/BR-0184

United States  
Nuclear Regulatory Commission



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# Regulatory Analysis Technical Evaluation Handbook

Draft Report

Office of Nuclear Regulatory Research

August 1993

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Q.3.

**NUREG/BR-0058**  
**Revision 2**



**United States**  
**Nuclear Regulatory Commission**

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# **Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission**

**Draft Report for Comment**

**August 1993**

QUESTION 4.

If enacted into law, how would the Act affect the Commission's present practices as described in question 3? If compliance with the Act would require additional resources in carrying out such practices, please estimate the additional resources (in terms of dollars and personnel) that would be required to carry out the provisions of the Act.

ANSWER.

- Even though the NRC believes that it already effectively meets the intent of H.R. 9, it is concerned that the proposed legislation is so highly prescriptive as to be potentially cumbersome and costly when put into practice. Implementation of the legislation may have the unintended consequence of confusing and impeding effective risk characterization and communication. The legislation would require long lists of factors that would need to be considered and presented in risk characterizations, such as multiple models, uncertainties, alternative biological endpoints, epidemiological and laboratory data, pharmacokinetic data, etc.

The overall objectives of Title 3 of H.R. 9 include a sound evaluation of risks, a balancing of costs and benefits, and appropriate peer review. These are objectives which the NRC not only endorses, but has already incorporated into its regulatory process. The NRC's Guidelines and Handbook, which were discussed in response to Q.3 above, not only address the need to assess risks and other cost benefit considerations,

QUESTION 4. (Continued)

- 2 -

but also contain detailed guidance on the use of methodological approaches to be used in their quantification. In addition, more than a decade ago, the NRC put into effect, for power reactors, the "backfit rule," 10 CFR 50.109, which requires a rigorous analysis before a more stringent requirement can be put in place unless that increased stringency is needed to provide "adequate protection of public health and safety." For any increase in protection over and above the statutory "adequate protection" standard, the backfit rule requires a demonstration that there is a "substantial increase" in overall protection, and that this increase in protection justifies the direct and indirect costs associated with the proposed regulatory requirement. Similar backfitting requirements apply to independent spent fuel storage facilities (10 CFR 72.62) and to gaseous diffusion plants (10 CFR 76.76). Although the backfit rule does not apply in the materials area, regulatory initiatives affecting materials licensees are subject to the full spectrum of NRC regulatory analysis requirements.

The NRC has also established a Committee for the Review of Generic Requirements to act as an internal control to insure that new requirements are justified. Scientific peer review is provided by the Advisory Committee on Reactor Safeguards, an independent advisory committee specifically established by statute as a peer review mechanism, and by other expert advisory committees, including the Advisory Committee on the Medical Uses of Isotopes, and the Advisory

QUESTION 4. (Continued)

- 3 -

Committee on Nuclear Waste. These committees typically review the technical and regulatory implication of proposed staff actions.

In short, there are already mechanisms that we consider extremely effective means of guaranteeing the scientific quality of new regulations, and of ensuring that any new requirements have passed through exacting scrutiny.

Further, the legislation would require extensive documentation of many aspects of risk assessment and risk characterizations, along with the consideration of a broader range of models and assumptions, peer reviews, and other activities. This would appear to increase resource needs for the NRC substantially.

Differences between current NRC practice and Title 3 that are likely to have resource implications are discussed below.

As noted before, depending on interpretation, the bill could be read to require comprehensive risk assessment in circumstances where NRC does not now do them and doesn't find them necessary. Beyond that even in circumstances where NRC would currently perform a risk assessment based on our initial review of Title 3, the following requirements will likely increase NRC resource requirements.

QUESTION 4. (Continued)

- 4 -

Section 3105: (also discussed in Section 3201)

- systematically include risk comparisons (risks familiar and routinely encountered by the general public)
- provide summaries of other risk estimates provided as a result of public comment

Section 3106:

- develop plan for assessing new information and prepare Congressional report
- revise NRC Guidelines and Handbook to ensure consistency with Presidential Guidelines and H.R. 9

If para (b) is interpreted as applying to all risk assessments prepared by the agency, regardless of their age, this could involve reviewing hundreds of closed actions and substantial agency resources.

Section 3201:

- certification that assessment and data used is unbiased and objective

QUESTION 4. (Continued)

- 5 -

certification of substantial improvement in public health and safety would be incremental for regulatory actions involving materials licensees

Section 3301:

No incremental resources anticipated based on the assumption that the NRC's existing expert advisory committees are viewed as satisfying Section 3301s peer review requirements.

There are many difficulties associated with an attempt to quantify the incremental resources associated with these requirements even if we assume the requirements apply to future circumstances where NRC would normally do a risk assessment analysis. As a rough ball park estimate, the staff estimates that each risk analysis/cost-benefit analysis would require approximately one man month of additional effort. Given that the NRC anticipates preparing approximately 40 of these analyses per year results in an annual increase in manpower of about 3 manyears (\$0.8 million). In addition, one time costs to update the NRC Guidelines and Handbook, and develop a plan and issue a Congressional report are estimated at 2 man years (\$0.5 million).

These cost estimates are viewed as highly uncertain as there are many factors that could cause these values to change dramatically. For

QUESTION 4. (Continued)

- 6 -

example, the NRC Guidelines emphasize flexibility and common sense in terms of the type of information and level of detail to be provided in any given regulatory/cost-benefit analysis. Factors that the staff should consider in determining the appropriate level of detail and effort include the complexity and policy significance of the problem being addressed, the magnitude and likelihood of the values and impacts, and the relative amount by which values and impacts differ. Thus, depending on the nature of the regulatory issue, the incremental resources necessary to comply with Title 3 could be significantly greater than those estimated here. In this regard, the NRC has a formal program in-place involving relaxations in regulatory requirements. It is unclear whether such relaxations would also be subject to the full set of requirements identified in H.R. 9. Further, H.R. 9 imposes additional contingencies that could extend the time and therefore resources needed to complete a regulatory action. For example, the requirement that the agency not only articulate its preferred choice, but also analyze alternative approaches and methodologies would seem to give parties endless room to challenge that an agency had failed to give sufficient attention to a particular theory, study, methodology, etc.

Finally, it should be noted that much of the regulation of nuclear materials occurs through 29 individual states, called Agreement States, with which the NRC has entered into agreements to discontinue NRC's regulatory authority to allow the states to regulate. These Agreement State programs must be "compatible" with NRC's regulatory program. The

QUESTION 4. (Continued)

- 7 -

Agreement States might well be required to conduct assessments, characterizations, and documentation similar to those the Act would mandate for NRC, to remain "compatible" with NRC's program under the new legislation. This could constitute an "unfunded mandate" on the States, unless the legislation is clarified to state that its requirements should not be transferred onto the States. Such an approach, however, could further complicate NRC's management of the NRC Agreement State program.

QUESTION 5.

How does the Commission obtain the information it uses to prepare risk assessments, cost-benefit analyses, or risk characterizations? Does the Commission rely in part upon the private sector in providing the information needed by the Commission to conduct such assessments or analyses? If so, would the Act require the Commission to obtain additional information from the private sector in order to comply with the Act's requirements?

ANSWER.

- The Commission's risk assessments typically use a mixture of information from internal sources and from the private sector (i.e., licensees). This information consists of, for example, design and operational characteristics of the facility being studied, submitted as part of a license application; operational information (equipment failures, events, etc.) submitted under agency rules as part of the monitoring of facility safety; handbooks of equipment reliability generated and published by industrial groups; and operational event reports from foreign regulatory organizations, as part of Commission foreign agreements. The amount of information needed from licensees would likely increase as a result of the Act in response to the need to perform assessments of uncertainties. (As discussed in the response to Question 7 below, the Commission is already working to increase the extent to which uncertainty analyses are performed in its risk assessments. As such, some additional information to support uncertainty analyses will likely be needed from licensees whether or not the Act becomes law.)

QUESTION 6.

Please identify the regulations expected to be prepared or promulgated in the next two years which would require a Regulatory Impact Analysis under Title VII, an analysis of risk reduction benefits and costs or a certification under Subtitle B of section 3201, or a peer review under section 3301. What additional procedures would the Commission be required to follow to issue such regulations if the Act were enacted into law? Would the Act permit judicial review of agency actions beyond what is presently permitted under the Administrative Procedure Act? Please estimate the additional time and resources that would be necessary to complete the expected rulemaking following the required procedures. If the Commission is subject to court-ordered or statutory deadlines for completion of any such regulations, can the Commission comply with the Act and still meet the such deadlines?

ANSWER.

- Title VII applies to major rules defined as rules that affect more than 100 persons or require expenditure of >\$1M by a licensee. We assume the drafters intended "affect" to relate solely to substantive impacts on the regulated community. If on the other hand "affect" includes impacts on the public at large who are the beneficiary of NRC actions, virtually every NRC rule would affect more than 100 persons. We are assuming the former interpretation.

QUESTION 6. (Continued)

- 2 -

The regulatory impact analysis required by this section is substantially the same as that which an NRC rule (which generally meets the above definition) currently goes through, with some significant additional requirements such as the provisions for hearings and OMB approval. On the basis of past experience on such matters, the additional time that would be necessary from such provisions could add up to years of time. If HR 9 had been in effect now, the following is an estimated list of rules currently on the NRC's regulatory agenda for the next two years that would be captured by the Title VII requirements. The requirements under Sections 3201 and 3301 are assumed to be met by the current normal agency practices, except as noted in our response to question 4.

## Example of Future Rules

Reactor Site Criteria; Including Seismic and Earthquake  
Engineering Criteria for Nuclear Power Plants (Parts 50, 52, 100)

Shutdown and Low-Power Operations (Part 50)

Codes and Standards for Nuclear Power Plants (ASME Code, Section  
XI, Division I, Subsection IWE and Subsection IWL (Part 50)

Primary Reactor Containment Leakage Testing for Water-Cooled Power  
Reactors (Part 50; Appendix J)

QUESTION 6. (Continued)

- 3 -

Radiography and Radiation Safety Requirements for Radiographic Operations (Part 34)

Requirements for Possession of Industrial Devices Containing Byproduct Material (Parts 31, 32)

Procurement of Commercial Grade Items by Nuclear Power Plant Licensees (Part 21)

Criteria for the Release of Patients Administered Radioactive Material (Parts 20, 35)

Radiological Criteria for Decommissioning of Nuclear Facilities (Parts 20, 30, 40, 50, 51, 70 and 72)

Frequency of Medical Examinations for Use of Respiratory Protection Equipment (Part 20)

Radiation Protection Requirements; Amended Definitions and Criteria (Parts 19, 20)

Interim Storage of Spent Fuel in an Independent Spent Fuel Storage Installation; Site-Specific License to a Qualified Applicant (Parts 2, 72)

QUESTION 6. (Continued)

- 4 -

Emergency Planning for Independent Spent Fuel Storage Facilities (ISFSI) and Monitored Retrievable Storage Facilities (MRS) (Part 72)

Design Certification Rule GE ABWR

Design Certification Rule - CE System 80+

Domestic Licensing of Special Nuclear Material (Part 70)

Update of Transportation Regulations to Incorporate New Licensing Information (Part 71)

The Commission would have at least the following, additional procedural requirements for rulemaking:

- preparation and issuance of an advance notice of rulemaking (90 days before publications of a proposed rule) (§ 7002)
- preparation and inclusion, to the extent possible, in the advance notice of rulemaking, of the information in the Regulatory Impact Analysis for each major rule (§ 7002)

QUESTION 6. (Continued)

- 5 -

- inclusion of a final Regulatory Impact Analysis in the general notice of the proposed rule, with a clear delineation of all changes from the information provided in the advance notice (§ 7002)
- provision of a hearing on a proposed rule, and determining what kind of hearing to provide, if more than 100 persons individually submit comments (§ 7003)
- **mandatory** extension of the comment period if more than 100 persons request and extension and **mandatory** delay of issuance of the rule during the additional 30 day period for comment (§ 7003)
- written approval of the final Regulatory Impact Analysis by the Director of OMB or an individual designated by the Director before the NRC could adopt the rule (§ 7005)
- to the extent practicable, obtain the certification of the Director of OMB, before publication of any proposed major rule, summary of a proposed rule, or Regulatory Impact Analysis, that the document meets the five standards of clarity and grammar set forth in § 7006

In their present form, neither Title III nor Title VII alters the general standards of the Administrative Procedure Act concerning the right of review

QUESTION 6. (Continued)

- 6 -

(5 U.S.C. § 702) and the scope of review (5 U.S.C. § 706). However, these Titles would impose numerous substantive and procedural requirements that would expand significantly the universe of specific issues upon which petitioner for judicial review could challenge agency action.

The NRC is not currently subject to court ordered or statutory deadlines for completion of rulemakings.

QUESTION 7.

Are the requirements of section 3105 for risk characterization (taking into account the definitions in 3106) consistent with the Commission's understanding of sound scientific principles for risk assessment and risk characterizations? Would the requirements of section 3105 preclude the Commission from considering any information, models, or assumptions in assessing or characterizing risk? How would the Commission be able to take into account risks to special subpopulations which may have higher susceptibility than "average"?

ANSWER:

- The proposed requirements for risk characterization in section 3105 are reasonably consistent with sound scientific principles for risk assessment and risk characterization. However, the focus of this section is exclusively human health risk assessment. In other words, these assessments would be conducted with the assumption that humans are exposed to some level of hazard or contaminant. As drafted, the section does not include or recognize the importance of considering the probabilities of exposure to radiation or of failure of engineered barriers (engineering risk assessment). Both of these considerations may be important in assessing actual risks to humans from hazardous materials and activities. In addition, the section excludes consideration of environmental (i.e., non-human) risks. Consideration

QUESTIONS 7. (Continued)

- 2 -

should be given to incorporating exposure probability and the more conventional definition of risk into the section (i.e., risk = probability x consequence), as well as environmental risks.

The Commission recently issued a draft policy statement (for public comment) on the agency's use of PRA. One of the four elements of the draft Commission policy was that risk assessments should be "as realistic as possible." The Commission also encourages the performance of uncertainty analyses as part of its risk assessments where practical within the bounds of the state of the art. As such, the requirements contained in section 3105, parts 1A and 1B appear to be consistent with sound scientific principles. The Commission's draft policy on "realism" would, however, not generally encourage the use of "plausible upper-bound or conservative estimates" noted in the paragraph immediately following parts 1A and 1B.

It does not appear that the act would preclude the Commission from considering information, models, or assumptions in its risk assessments.

The Commission's established measure of risk benefit (for power reactor issues) is the collective dose to the total population within fifty miles of a reactor site. Reflecting this measure, the Commission's risk assessments do not typically discuss risks to subpopulations (i.e., one

QUESTION 7. (Continued)

- 3 -

dose-response model is used for all exposed individuals)<sup>1</sup>.

Conceptually, the Commission's models for estimating population dose could account for subpopulations. However, to accomplish this in practice would require some modifications to the existing model.

Other measures of risk used by the NRC besides collective dose to populations within 50 miles of a reactor are used in NRC's many other regulatory programs. For example, risks in decommissioning or radioactive waste disposal may be assessed in terms of collective dose to a critical population group representing people who may live in the near vicinity of former nuclear facilities. In these programs, risks to special subpopulations (e.g., minorities, institutionalized persons) could still be considered through the analysis of whether doses or emissions are as low as reasonably achievable in accordance with 10 CFR 20.1101(b) and in evaluating potential environmental impacts in accordance with 10 CFR Part 51 and the National Environmental Policy Act.

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<sup>1</sup>

The dose criteria established as limits in the Commission's regulations include different limits for specific subpopulations, e.g. minors and radiation exposure of embryo/fetus. These criteria are established based on risk-based analyses by the International Commission on Radiological Protection, the National Academy of Sciences, National Council on Radiation Protection and Measurements, etc.

QUESTION 7. (Continued)

- 4 -

Section 3105(1) of the Act appears to require the best estimate of risk, which is defined in Section 3107(3) as an average or central estimate of risk. This could be interpreted as precluding regulatory measures to protect highly-sensitive populations, protected under current health-physics practices in use by the NRC. For example, lower exposure limits for children, fetuses, and women of child-bearing age might be disallowed. Also, higher exposure limits for radiation workers might be disallowed and the lower general population limits substituted.

Substitution Risk, although a simple concept, may be very difficult to implement. NRC often has to trade-off exposure (hence risk) reductions to the public with increased exposure (hence risk) to workers. NRC could have difficulty comparing different strategies that resulted in different risks to (1) the public, (2) the workers, (3) the facility, (4) the environment. These do not have the same risk measure (e.g. mortality, dollars, pollution). Further, in waste management, NRC considers intergenerational risks. Balancing risks and benefits of this generation against those of future generations is expected to be challenging.

QUESTION 8. To the extent not already addressed in previous answers, please identify all risk assessment documents, regulatory proposals or decisions, reports to Congress, or other documents made available to the public by the Commission which include characterizations of risks that would be subject to the requirements of section 3105.

ANSWER:

- In addition to risk assessments performed for cost-benefit analyses, the Commission sometimes performs risk assessments to characterize its estimates of present risks from power reactors (e.g., the 1991 report NUREG-1150) or to demonstrate new risk assessment methods. Such assessments would appear to be subject to the requirements of section 3105.

QUESTION 9.

Please estimate the cost of complying with the peer review requirements of section 3301, taking into account the provisions of Title VII requiring Regulatory Impact Analyses. How would the Commission implement the requirement for peer review of "economic assessments," "economic information," and "cost assessments?" Would the Commission be precluded from issuing any regulation until the required peer review, peer review report, and response to the peer review, had been completed and made available to the public? How long would such a process be likely to take? Would such peer review panels be subject to the Federal Advisory Committee Act?

ANSWER:

- Under most circumstances, it is anticipated that the NRC's existing advisory committees could satisfy the peer review requirements with no incremental costs to the NRC. This should be clarified in the legislation. However, it is recognized that there may be unique circumstances where a particular regulatory initiative could require such extensive peer review that the peer review requirements specified in H.R. 9 when applied to an individual regulatory action could result in incremental costs on the order of \$1 million.

H.R. 9 appears to contemplate completion of the peer review process as a condition for the issuance of a "major" rule. Section 3301(b), in Subtitle C of Title III, indicates that each Federal agency must obtain

QUESTION 9. (Continued)

- 2 -

peer review for purposes of the assessment of costs and benefits that underpin the issuance of a final rule as well for purposes of any significant risk or cost assessment prepared "in connection with a major rule."

Since both Subtitle B of Title III and provisions of Title VII impose substantial risk and cost assessment requirements at the advanced or proposed notice of rulemaking stages, it seems that H.R. 9 would require that an agency address significant peer review comments on "major rules" before issuing the regulation. In addition, section 3301 specifically provides that all peer review comments or conclusions and the agency's responses shall be made available to the public and shall be made part of the administrative record for purposes of judicial review of any final agency action.

The peer review panels would be subject to the Federal Advisory Committee Act. The provisions in the legislation governing the operation of the peer review groups are consistent with the current provisions of that Act. The Nuclear Regulatory Commission could use its existing advisory committees to perform the required peer reviews.

It is extremely difficult to attach a representative time period to the peer review process because it depends so intimately on the complexities of the issue at hand. For example, the NRC is currently utilizing the

QUESTION 9. (Continued)

- 3 -

unique expertise within the National Academy of Sciences for a peer review on the use of digital control systems in nuclear power plants. This peer review could likely take as much as two years.

PRELIMINARY COMMENTS ON SELECTED TITLES OF H.R. 9

## A. "TITLE III -- RISK ASSESSMENT AND COST/BENEFIT ANALYSIS FOR NEW REGULATIONS"

The overall objectives of this title of the proposed law -- a sound evaluation by agencies of the risks at which regulations are directed; a sensible balancing of costs vs. benefits, to ensure that new regulations are justified; and appropriate peer review to ensure the scientific validity of regulatory approaches -- are ones which the Nuclear Regulatory Commission not only endorses, but has already incorporated into its regulatory processes. For example, the NRC more than a decade ago put into effect, for power reactors, the "backfit rule," 10 CFR § 50.109, which requires a rigorous analysis before any backfitting (which may be defined loosely as an increase in the stringency of regulation) can take place, unless that increased stringency is needed to fulfill our statutory mandate to provide "adequate protection of public health and safety". (It should be noted that if, for example, new information comes to light that makes it apparent that "adequate protection of public health and safety" can only be ensured by a new regulation, the Atomic Energy Act mandates the issuance of such a regulation). For any increase in protection over and above the statutory "adequate protection" standard, the backfit rule requires a demonstration that there is a "substantial increase" in overall protection, and that this increase in protection justifies the direct and indirect costs to the regulated party.

The NRC also established a "Committee for the Review of Generic Requirements" to act as an internal control, insuring that new requirements are justified. Scientific peer review is provided by the Advisory Committee on Reactor Safeguards, an independent advisory committee specifically established by statute as a peer review mechanism, and by other expert advisory committees, including the Advisory Committee on the Medical Uses of Isotopes and the Advisory Committee on Nuclear Waste.

In short, there are already mechanisms that we consider extremely effective means of guaranteeing the scientific quality of new regulations, and of ensuring that any new requirements have passed through exacting scrutiny.

Title III of the proposed legislation, on the other hand, may have some requirements that are so highly prescriptive as to be potentially cumbersome and costly when put into practice. (Since the NRC is required by law to collect approximately 100% of its operating costs from the regulated industry, these additional costs would then be passed on to our licensees). For example, the requirement that the agency not only articulate its preferred choice, but also analyze alternative approaches and methodologies, would seem to give parties almost endless room to argue that an agency had failed to give sufficient attention to a

ENCLOSURE 2

particular theory, study, or methodology. While the assumption underlying the bill seems to be that these procedural requirements would serve to protect the regulated industry by raising obstacles to unnecessary new regulations, it appears that these provisions could be used with some ease by persons demanding additional regulation. The costs of meeting all such procedural requirements would ultimately be passed on to the regulated industry. Likewise, the cost of the independent peer review panels -- which might in many cases be unnecessary, where the scientific basis of the agency's approach was not controversial -- would be borne by the regulated industry.


In short, there is reason for concern that Title III might have some effects contrary to those intended by its proponents, given the extent to which its objectives are already satisfied by existing NRC regulations and policies.

B. "TITLE IV -- ESTABLISHMENT OF FEDERAL REGULATORY BUDGET COST CONTROL"

Title IV of the legislation is designed to limit the extent to which regulatory agencies can impose cost burdens on the private sector, both in the aggregate, through the totality of the agency's regulations, and through analyses of individual rules and regulations.

It is difficult to assess the effect of Title IV on the programs and activities of the NRC because of the unique historical relationship between the regulators and the regulated industry in the nuclear field. The legislation seems to take as its starting point the model of a business capable of operating by itself without governmental intervention or interference. In such a case, the cost of complying with governmental regulation may be estimated with greater or lesser precision. In the case of entities regulated by the NRC -- in particular, nuclear power plants -- this model is of limited relevance, assuming that Congress and the public desires the nuclear industry to remain closely regulated.

Similar problems occur in trying to estimate the absolute cost of new regulations. Where a regulation is a backfit that is not essential to maintain "adequate protection," but is instead designed to upgrade further a plant that is already acceptably safe, then the costs of the new regulation may be computed relatively easily. In such a case, the choice is between operating with and without the regulatory upgrade. However, when newly developed information shows that a particular backfit is necessary in order for a plant to continue safe operation, then the alternative to operating with the backfit is not to operate at all; thus it is difficult to calculate in a meaningful way the cost of complying with the new regulation.



For all these reasons, we believe that provision should be made in the legislation to take into account the NRC's statutory mandate to ensure "adequate protection of public health and safety" in view of the fact that the NRC does not have the same kind of discretion that many other agencies possess to choose whether or not to issue particular regulations. A system of regulation that puts health and safety first cannot be fully reconciled with a statutory requirement geared to cost impacts on regulated entities.

C. "TITLE VII -- REGULATORY IMPACT ANALYSES"

This title would amend the Administrative Procedure Act. Among its most noteworthy provisions, it would require:

- an advance notice of rulemaking (90 days before publication of general notice of a proposed rule), including, to the extent possible, the information in the Regulatory Impact Analysis (see below) for each major rule (affecting more than 100 persons or requiring a \$1 million expenditure by any person);
- inclusion of a final Regulatory Impact Analysis in the general notice of the proposed rule, with a clear delineation of all changes from the information provided in the advance notice;
- a hearing (of unspecified form) on a proposed rule if more than 100 interested persons individually submit comments;
- 30-day extension of the comment period if more than 100 persons individually request an extension;
- application of Executive Order 12291 (regulatory impact analysis, review and coordination) to each agency;
- a Regulatory Impact Analysis, both in preliminary and final form, that contains 22 specified analyses, including: (a) a cost-benefit analyses; (b) a demonstration that the rule provides the least costly or least intrusive approach for meeting its intended purpose; and (c) an estimate of costs to the agency for implementation and enforcement;
- written approval of the final Regulatory Impact Analysis by the Director of OMB or an individual designated by the Director before an agency may adopt a major rule;

- written certification by the Director of OMB that any proposed major rule for publication meets 5 standards of clarity.

The most dramatic aspect of this title is the requirement that OMB approve the Regulatory Impact Analysis of the agency before the agency can adopt a major rule. This title does not appear to contain any savings or override provision for independent federal agencies of the kind that is found in the Paperwork Reduction Act or in Title III of this bill. Consequently, the agency's independence could be undermined in its normal rulemaking processes for major rules.

The provisions of this subtitle may slow the regulatory process for major rules considerably. First, there is likely to be uncertainty about whether any possible error or lack of clarity in the Regulatory Analysis, or any issue discussed in it or omitted from it, will lead to litigation. Second, although much if not most of the required analysis is already performed in some fashion by this agency, the bill also adds detail and formality that will cost considerable time and resources. Here again, the result could well be contrary to the intention of the bill's drafters. Much of NRC's rulemaking activity is now devoted to removing regulations found to be unnecessary or unduly burdensome. The legislation in its present form could slow down the process of diminishing excessive regulatory burdens.

#### D. "TITLE VIII -- PROTECTION AGAINST FEDERAL REGULATORY ABUSE"

##### Subtitle A -- Citizens' Regulatory Bill of Rights

This subtitle would require Miranda-type warnings (the right to remain silent and have an attorney or accountant present, when an agency initiates an inspection, investigation, or other proceeding against a person who is "the target of a Federal investigative or enforcement action." It also provides certain rights to damages for unreasonable Government actions and to attorneys fees for frivolous civil actions initiated by the Government against the target.

The bill fails to define "target" or the nature of the "Federal investigative or enforcement action." This should be clarified. If it means criminal investigative or enforcement action, DOJ is the lead agency insofar as the NRC is concerned and its comments should be solicited.

If the bill intends to require such warnings in connection with civil administrative inspections or investigations, it could significantly hamper the effectiveness and efficiency of some NRC cases. It reads as if such warnings must be given upon the initiation of an inspection or investigation, whether or not the

person who is the target is about to be interviewed. It would provide a right to remain silent, even though the inspection or investigation is civil and administrative in nature. It would require disclosure of the scope or purpose of an investigation upon its initiation, even though such disclosure might in some circumstances have an adverse effect on the investigation, e.g., by making possible the destruction of evidence. It also raises the question of whether the NRC would have to advise individuals and/or licensees of the right to have a lawyer present even when it conducts routine inspections, or whenever the NRC inspects for a violation that it has reason to believe has been committed -- and perhaps even when an agency interviews a witness regarding the suspected violation.

In short, as drafted the scope of this subtitle is uncertain and the meaning of its provisions are vague and uncertain. Therefore, the impacts of its provisions are difficult to assess. Nonetheless, it appears that the subtitle could be interpreted in such a broad fashion as to add significant restrictions on agency investigations and inspections that have not heretofore been imposed by Congress or by the courts and that could hamper the effectiveness and efficiency of some NRC investigations and inspections. It seems quite possible, moreover, that the legislation could have a serious impact on the NRC's inspection program, all the more so because a key element of NRC's regulation of nuclear power plants is the presence of resident inspectors, who deal with licensees continuously, and indeed are available on a round-the-clock basis. To work as it should, the relationship between the inspectors and the licensees must be one of frequent and free communication, not impeded by complicated procedural requirements.

#### Subtitle B -- Private Sector Whistleblowers' Protection

This subtitle prohibits agencies and agency employees from acting (or "refusing to take action") where such action (or refusal to take action) is a form of retaliation against a "whistleblower" in the private sector. Specifically, the bill bars regulatory action from being taken (or withheld) "because of any [person's] disclosure" of information that the person believed was indicative of mismanagement, waste, inconsistent enforcement, or certain other inappropriate or illegal actions by the agency. The bill characterizes such actions as "prohibited regulatory practices" and permits the persons who made such disclosures to raise as a defense, in any proceeding initiated by the agency, "a prohibited regulatory practice with respect to the person or to a related entity in connection with the action or proceeding."

If a prohibited regulatory practice is established, no penalty or fine may be assessed against the person who asserted the defense. In addition, the agency or the employee who engaged in a

prohibited regulatory practice may be assessed a civil penalty of \$25,000 or less for each day on which the prohibited regulatory practice continued.

Any person who is injured or threatened by a prohibited regulatory practice may commence a civil action for injunctive and declaratory relief, and compensatory damages including legal and expert fees. Such a person may also obtain punitive damages in an amount not to exceed \$25,000 for each day of each prohibited regulatory practice.

The bill provides that any action shall be deemed to have resulted from such a disclosure of information if the disclosure of information was a contributing factor to the decision to take or not to take action. It also authorizes citizen complaints of prohibited regulatory practices to the Office of Special Counsel which may investigate the allegation with the same investigative powers as it exercises for prohibited personnel practices.

Agency enforcement or other regulatory action against a person because of the person's complaint about agency mismanagement or impropriety is obviously improper. However, it is not clear to the NRC that such retaliatory agency action is a wide-spread problem or that the existing administrative and judicial mechanisms for review of such allegations are inadequate.

It seems quite likely that the agency would face one or more improper regulatory practice defenses in nearly every case. Consequently, the NRC's ability to protect public health and safety would likely be diminished by virtue of the distractions, inefficiencies and costs of defense associated with the elaborate procedures and remedies that are proposed.

Claims for penalties against individual agency employees would likely have a chilling effect on the willingness of agency employees to enforce agency regulations vigorously and would inject substantial complexity into the defense of an agency's enforcement action. The legislation does not spell out whether agency employees would be represented by Government counsel in suits brought against them under this Title. It should be noted that the bill does not provide for reimbursement of the government's costs when it prevails against unfounded charges of improper regulatory practice.

Currently, in cases where there is an allegation that action against a private party was taken because of a retaliatory motive by a Federal employee, the agency may still prevail if it can show by clear and convincing evidence that it would have taken the action even in the absence of any retaliatory motive. The subtitle of the proposed legislation seems to provide more definitive and drastic consequences, in terms of limiting the Government's ability to take needed regulatory action, whenever a

showing can be made that a protected disclosure of information by someone in the private sector was a "contributing factor" in the challenged agency decision. Consideration should be given whether so extreme a remedy is necessary or desirable, especially where public health and safety issues are involved.

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*Draft*

**White Paper on Risk Harmonization**

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U.S. Nuclear Regulatory Commission  
U.S. Environmental Protection Agency

*January 1995*

## White Paper on Risk Harmonization

## 1.0 INTRODUCTION

1.1 Statement of the Problem

Authority for protection of members of the public from exposure to radioactive materials was divided in 1970 between the newly-created Environmental Protection Agency (EPA) and the former Atomic Energy Commission (AEC). The Reorganization Plan (No. 3 of 1970, Sec. 3, para. 6) through which EPA was created provided that, henceforth, EPA would set generally applicable environmental standards and that AEC would implement and enforce those standards<sup>1</sup>.

Over subsequent years, EPA has undertaken a number of regulatory initiatives under its authorities that affect activities licensed or otherwise regulated by the Nuclear Regulatory Commission<sup>2</sup>. In the course of developing these initiatives, substantial disagreements have arisen between the two agencies over (1) the respective roles for EPA and NRC in the regulation of NRC-licensed facilities<sup>3</sup>, (2) the benefit of these various initiatives in terms of providing additional protection beyond that already afforded by NRC's regulatory program<sup>4</sup>, and (3) their relative timing and priority. Furthermore, disagreements have occurred over the underlying bases and approaches used to develop specific standards. These disagreements have been complicated by the enactment of a series of environmental statutes that extend beyond regulation of radioactive material, including: Comprehensive Environmental Response, Compensation and Liability Act (CERCLA); Safe Drinking Water Act (SDWA); Resource Conservation and Recovery Act (RCRA); Toxic Substances Control Act; Clean Air Act (CAA); and Federal Water Pollution Control Act (FWPCA). The regulatory programs developed under these separate statutes create the potential for conflicting approaches to environmental protection and have significantly affected

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<sup>1</sup> The President's transmittal of the Reorganization put it as follows: "The AEC is now responsible for establishing environmental radiation standards and emission limits for radioactivity. Those standards have been based largely on broad guidelines recommended by the Federal Radiation Council (FRC). The AEC's authority to set standards for the protection of the general environment from radioactive material would be transferred to the EPA. The functions of the FRC would also be transferred [to the EPA]. AEC would retain responsibility for the implementation and enforcement of radiation standards through its licensing authority."

<sup>2</sup> NRC and the Department of Energy are successors to the AEC.

<sup>3</sup> As the term "NRC-licensed" is used throughout this document, it also includes facilities licensed by Agreement States pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

<sup>4</sup> Disagreements have also arisen regarding whether NRC's overall regulatory program (including implementation and enforcement aspects) or only its enforceable requirements can be considered in demonstrating achievement of the same level of protection as EPA's numerical standards.

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EPA's development of standards under the Atomic Energy Act of 1954, as amended (AEA)<sup>5</sup>.

Disagreements that have occurred between the two agencies have diverted attention from our mutual objective of protecting public health and safety and the environment, have unnecessarily consumed limited public and private resources, and have eroded public confidence in our respective regulatory programs and in the activities we regulate. Recognizing this problem and the need to ensure consistency in Federal regulation of radioactive material, NRC and EPA signed a Memorandum of Understanding (MOU) in March 1992. The MOU provided a formal mechanism for agency cooperation on issues relating to environmental regulation of radionuclides subject to NRC authority. It also committed the agencies to "...actively explore ways to harmonize risk goals and ... [to] cooperate in developing a mutually agreeable approach to risk assessment methodologies for radionuclides." This paper represents an initial response to the MOU's directive and is intended to provide the agencies' joint examination of the similarities and differences in their approaches to assessing and managing risks.

## 1.2 Background

After the establishment of EPA in 1970, the AEC, and later NRC, continued to exercise standards functions in parallel with EPA's exercise of its authority. In the early to mid-1970s, the agencies attempted to refine their division of responsibilities<sup>6</sup>. During this period, environmental legislation continued to exclude radioactive materials regulated under the AEA (e.g., RCRA). With the 1977 amendments to the CAA, Congress allowed a significant departure from the general concept of a single Federal agency with implementing and enforcement jurisdiction over AEA materials. EPA, which was already charged to promulgate National Emission Standards for Hazardous Air Pollutants (NESHAPS), listed radionuclides as a hazardous air pollutant under section 112 of the CAA. Thus, through the CAA, EPA became responsible for implementing and enforcing these standards at NRC licensee sites. In addition, the CAA permits the States to promulgate more restrictive standards. Subsequently, Congress also gave EPA responsibility for standards setting and/or

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<sup>5</sup> These difficulties were recently highlighted when EPA, under the Clean Air Act Amendments of 1977 (CAA), listed radioactive materials as hazardous air pollutants and established emission limits in 1989. These limits are a factor of 10 times more restrictive than corresponding NRC limits under the AEA.

<sup>6</sup> In 1973, AEC turned to the Office of Management and Budget (OMB) to resolve which agency should have the responsibility for issuing standards to define permissible limits on radioactivity that may be emitted from facilities in the nuclear power industry. On December 7, 1973, OMB issued a memorandum to the Administrator of EPA and the Chairman of AEC, stating, in part, that AEC should continue issuing uranium fuel cycle standards, taking into account comments from all sources, including EPA, and that EPA should continue to have responsibility for setting standards "...for the total amount of radiation in the general environment from all facilities combined in the uranium fuel cycle...". EPA set such standards in 1977 (40 CFR Part 190), which NRC has incorporated into its regulations.

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regulatory implementation for radioactive materials, under several other statutes (e.g., Uranium Mill Tailings Radiation Control Act (UMTRCA), CERCLA, and Waste Isolation Pilot Plant Land Withdrawal Act (WIPPLWA)).

There are three areas of concern that arise as a result of the statutory authorities and distribution of responsibilities described above. The first two involve the regulation of radioactive materials only; they are 1) the establishment of inconsistent standards for protection of members of the public and the environment, and 2) the uneven implementation and enforcement of those standards at individual licensee sites. The third area of concern is: (3) the inconsistency of regulation of hazardous chemicals and radioactive materials. There is no distinction between these two classes of hazardous substances in the majority of environmental statutes. EPA risk management for radioactive materials under these statutes has been strongly driven by the numerical risk standards and policies established for hazardous chemicals that are potential carcinogens.

The overlapping implementing and enforcement jurisdiction, together with differing statutory mandates and agency objectives, priorities, and procedures have resulted in both real and perceived differences between NRC and EPA over the regulation of radiation in the environment and inconsistent regulation of radiological and nonradiological risks. Over the course of the past several years, EPA and NRC have had different views on how best to proceed, with a number of standards or guidelines, to address the hazards associated with commercial uses of nuclear materials, including: (1) emission limits under the CAA, (2) general environmental standards for low-level waste management and disposal facilities, (3) standards for uranium mill tailings management and disposal, (4) standards for wastes considered "below regulatory concern," (5) standards for the management and disposal of high-level waste, (6) standards for offsite exposures from fuel cycle facilities, (7) protective action guidelines for emergency planning at nuclear facilities, (8) standards for allowable residual radioactivity at contaminated sites, (9) guidance for occupational exposures to ionizing radiation, and (10) guidance for public exposure to ionizing radiation. Resolution and agreement have been reached on some, but many issues remain on the bases for these standards and guidelines and their implementation.

### 1.3 NRC/EPA 1992 MOU

NRC and EPA signed an MOU on March 16, 1992, that established a framework for resolving issues of joint NRC-EPA concern that relate to the regulation of radionuclides in the environment, excluding matters arising under RCRA or CERCLA. Because differences in risk assessment and management approaches appeared to be a root cause for several priority issues, NRC and EPA agreed that exploration of risk harmonization would be beneficial to both agencies. The MOU, therefore, in addition to providing a framework for continued cooperation in resolving high-priority issues, commits the agencies to actively

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explore ways to harmonize risk goals, and to cooperate in developing a mutually agreeable approach to risk assessment methodologies. To meet this commitment, the two agencies began, in 1992, to explore generically the treatment of risk in their programs.

#### 1.4 Approach and Scope of This Project

The agencies used a two-phased approach for their generic exploration of risk harmonization. The first phase consisted of an examination of approaches to risk **assessment** (primarily radiological) used in each agency. The second phase involved a similar examination of risk **management** approaches. To provide a comprehensive generic review, risk management approaches used by EPA under RCRA and CERCLA were included because the policies under these statute strongly influence EPA's risk decisions and reflect the implementation of EPA programs.

For this exploration, the agencies define **risk assessment** as a process that includes methods, assumptions, and other considerations involved in the description and quantification of a potential risk from a particular activity or situation. In contrast, **risk management** is the judgmental policymaking process that leads to regulatory decisions, such as: (1) the selection of risk limits, source or pathway constraints, standards or goals, and the methods to achieve their implementation (which includes consideration of the robustness, precision, or uncertainties in risk assessments); and (2) the selection of regulatory preferences, among risk reduction alternatives, that may include consideration of costs, as well as other factors.

The concept implicit in this set of working definitions is to differentiate between quantification of risk (**risk assessment**) and the judgmental activity of selecting acceptable risk levels followed by setting implementing standards and regulations that limit risks and impose costs (**risk management**). In theory, the risk embodied in a given situation would be similarly assessed, if certain parameters associated with potential exposure scenarios are defined. However, agencies with different regulatory viewpoints might not necessarily reach the same risk management outcomes.

Each agency systematically examined the approaches it used in a representative spectrum of its own programs and applications. The approaches were then compared and contrasted to identify similarities and differences in approaches for risk assessment and risk management between the two agencies.

In profiling risk assessment and management methods, NRC and EPA agreed that the scope would be broad, but not totally inclusive, in terms of program areas and types of assessments. Several different types of risk assessment and management applications were identified, generally including those in support of rulemakings and compliance

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determinations, but, at this point, excluding programs directed solely at accidents or abnormal events.

Tables A and B show the programs from each agency that were reviewed for this project, paired when both EPA and NRC have programmatic responsibilities with corresponding or similar scopes.

**Table A - Paired Programs Assessed**

NRC	EPA
Decommissioning	Superfund
Low-Level Waste Disposal	Low-Level Waste Standards
High-Level Waste Disposal	High-Level Waste Standards
Byproduct and Source Material, and Reactor and Fuel Cycle Air Emissions	NESHAPs (40 CFR Part 61)
Uranium Mill Tailings Licensing	Uranium Mill Tailings Standards
Reactor and Fuel Cycle Licensing	Uranium Fuel Cycle Standards

**Table B - Other Programs Assessed**

NRC	EPA
Radiation Protection Standards (Part 20)	Occupational Guidance (reference only)
Byproduct Material Licensing	Drinking Water Standards, Groundwater Protection Strategy

The comparison between agencies focused on health risk assessment approaches and techniques. It did not address engineering risk assessment, which considers the probability and consequences of failure of components and structures, although such assessments can affect environmental decisions.

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### 1.5 Organization of the Report

Section 2 presents findings and conclusions in the comparison of **risk assessment** approaches used by the two agencies. Similarly, Section 3 contains a discussion of **risk management** approaches. The concluding chapter summarizes what has been learned from this investigation. The report is founded on the premise that harmonization of risk assessment and management approaches between the agencies is a desirable goal that is consistent with the EPA/NRC MOU. The appendix (under development) contains tables that summarize the **risk assessment** and **risk management** approaches employed in the individual programs.

## **2.0 RISK ASSESSMENT**

The objective of the risk assessment comparison was to identify significant similarities and differences in the approaches used by EPA and NRC in the quantification of risk (primarily radiological), and to highlight issues that require further exploration.

Staff from both agencies first identified NRC and EPA programs with largely similar or corresponding scopes (i.e., those shown in Table A), then addressed the other programs identified in Table B. Each program was examined according to a list of characteristics that form the basis for risk assessment in each program area:

- Application of the risk assessment ( e.g., compliance assessment, standards, rulemaking)
- Assessment methodology: deterministic or probabilistic
- Exposed population considered ( e.g., maximum exposed individual, maximum reasonably exposed individual)
- Exposure scenario(s) considered ( e.g., onsite resident, nearest individual)
- Critical pathways ( e.g., inhalation, resuspension, direct radiation)
- Critical assumptions: key factors, driving parameters
- Computer codes employed
- Other issues or important aspects

The findings from this comparison of programs are included in Table 1 of the appendix (under development). The remainder of this chapter discusses the key similarities and differences between and across the agencies.

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## 2.1 Similarities

The comparison showed that, in many respects, EPA and NRC assess risk in the same way. The specific similarities identified are outlined below:

**Both agencies use cancer mortality and/or morbidity as primary measures of health risk for contaminants.**

Both agencies report numerical values of risk primarily in terms of cancer fatalities and/or morbidities (e.g., EPA--radiation, RCRA, and CERCLA). Although acknowledging that other risks exist (e.g., genetic effects, birth defects), they are often not numerically quantified in the risk assessments. The Federal Radiation Protection Guidance for Occupational Exposure is an exception- it explicitly specifies limits to protect the embryo/fetus against potential birth defects associated with radiation. NRC's 10 CFR Part 20 implements these limits for the declared pregnant worker.

**Translations between dose and risk usually use international consensus factors.**

In analyses done by NRC and EPA, the conversions of unit intake of a radionuclide through inhalation or ingestion into a dose or risk rely, for the most part, on factors that are broadly accepted. Both agencies make use of recommendations from the International Commission on Radiological Protection (ICRP), National Council on Radiation Protection and Measurements (NCRP), and the National Academy of Sciences (the Biological Effects of Ionizing Radiation (BEIR) reports). Differences between the two agencies usually involve minor variations, although some significant differences in dose conversion factors for a few radionuclides (primarily  $\alpha$ -emitters) exist, and are discussed in Section 2.2.

**In generic rulemaking and standard-setting activities, both agencies frequently assess exposure to a "reasonably" maximum exposed individual (e.g., average member of a critical group or "95th percentile Individual"). However, NRC effluent concentration values, tabulated for use in compliance demonstrations, are based on a theoretical maximum individual located at the boundary of the unrestricted area<sup>7</sup>.**

Both NRC and EPA, for assessments used in calculating risk to individuals, calculate the exposure to a hypothetical "reasonably maximum exposed individual." A hypothetical individual is assumed because of uncertainties about whether an individual will be subjected to the risk. For example, in evaluating potential exposures to residual contamination, it is

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<sup>7</sup> See 10 CFR 20.1302(b)(2) and referenced Appendix B concentration values.

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typically assumed that a future individual may be exposed to the contamination through a variety of pathways (e.g., resident farmer scenario). Conceptually, such an approach endeavors to strike a balance between limiting the maximum risk to most of the population and protecting all individuals, without resorting to patently implausible or highly unlikely scenarios that incorporate extreme conservatism. As difficult as it may be to define the term "reasonably," this approach acknowledges the need for credibility in defining applicable scenarios.

In certain programs, the reasonably "maximum exposed individual" construct is replaced by a less-ambiguous, although highly time-dependent, definition. EPA's uranium fuel cycle standards<sup>8</sup> specify that compliance determinations can consider actual individuals, based on the situation at the time of the evaluation. Similarly, the NESHAPs standards program applies to actual individuals<sup>9</sup>. In both cases, however, the individual targeted by the relevant EPA standard can be replaced, at the discretion of the licensee, by a more conservative "maximum exposed individual." Similar flexibility exists for demonstrating compliance with NRC's public dose limits<sup>10</sup>.

**Both agencies use deterministic risk (dose) assessments, but each also uses probabilistic assessments in selected programs.**

Both EPA and NRC use deterministic exposure scenarios (i.e., combinations of exposure assumptions and presumptions on populations exposed) in performing dose/risk assessments in most of their programs. For a specific application in a given program (e.g., decommissioning, Superfund), appropriate scenarios are usually defined. These scenarios are frequently deterministic; there is no explicit accounting for probabilities of occurrence. Instead of incorporating probability distributions into the algorithms used for dose/risk assessment, both agencies address uncertainties in the exposure situation by examination of alternative deterministic scenarios to assess parametric sensitivities.

In contrast to the above, certain programs explicitly use or are planning to consider probabilistic methods in their risk/dose assessments. High- and low-level (NRC) radioactive waste disposal programs use or are considering the use of sophisticated stochastic modeling, to express a full range of anticipated and projected events and parametric variations, as well as their probabilities of occurrence. The high-level waste programs in both agencies review repository designs against man-caused and natural processes and events (external events).

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<sup>8</sup> See 40 CFR Part 190.

<sup>9</sup> See 40 CFR Part 61.

<sup>10</sup> See 10 CFR 20.1302(b)(1).

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These analyses assess behavior of the repository, and resulting doses, for a range of possible release scenarios, over an assumed 10,000-year lifetime of the repository. Although not specifically considered in this paper, it should be noted that NRC's reactor program evaluates reactor designs by assessing possible releases from a design-specific probabilistic risk assessment. These assessments are used by EPA in deriving protective action guides for accidents.

**Both agencies usually consider the same pathways of exposure.**

In general, both agencies draw from the same possible exposure pathways for their analyses. The relative significance of a particular pathway in the risk assessments depends on source, environmental, and population characteristics. Frequently, one pathway will "dominate" the analysis (i.e., contribute the most to the potential dose or risk). In those cases, that pathway may become the target for sensitivity analyses, or may be the controlling pathway that results in a recommended specific regulatory action (e.g., inhalation of radon).

NRC regulations include explicit concentration limits, for air and water pathways, as a mechanism for demonstrating compliance with the dose limits for members of the public<sup>11</sup>. The concentration limits can be applied at the unrestricted area boundary, but, in practice, are frequently compared with concentrations at points of discharge. Their use is conditional (i.e., external dose rates cannot exceed 2 millirem/hour (0.02 mSv/hour) or 50 millirem/year (0.5 mSv/year)) and procedures and engineering controls must be used to achieve doses that are as low as is reasonably achievable (ALARA)<sup>12</sup>. Explicit concentration limits are also provided for sewer disposal. EPA also sometimes requires compliance with specific concentration limits to ensure protection of the public (e.g., drinking water standards in 40 CFR Part 141).

For other NRC programs, significant pathways and parameters are generally considered such as those outlined in NRC's Regulatory Guide 1.109 or NUREG/CR-5512. These programs include low-level and high-level waste disposal and decommissioning. EPA's standards also consider these same pathways and may allow flexibility to consider site-specific factors that determine risk. The best example for air and related pathways is the collection of codes used for compliance with the National Emission Standards for Hazardous Air Pollutants for radionuclides in 40 CFR Part 61. The CERCLA (Superfund) program has also published extensive guidance for evaluating exposure pathways relevant to contaminated soil, and ground and surface water contamination.

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<sup>11</sup> See 10 CFR 20.1302(b)(2) and referenced Appendix B concentration values.

<sup>12</sup> See 10 CFR 20.1101(b).

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**Both agencies truncate risk assessments in time, for technical reasons.**

Although both agencies truncate dose calculations, in time, for technical or policy reasons, this is usually carried out only when this action is demonstrated to have no significant impact on the regulatory decision being made. For example, certain programs have made policy decisions to truncate at times beyond which the effectiveness of control options ceases or is no longer assessable. Among NRC programs, low-level waste, decommissioning, and uranium mill tailings truncate their analyses at 1000 years. In 1993, EPA determined in its high-level and transuranic waste standards at 40 CFR Part 191, applicable to the Waste Isolation Pilot Plant and sites other than Yucca Mountain, that individual doses, groundwater concentrations and cumulative releases should be assessed over 10,000 years<sup>13</sup>. EPA truncates all of its low-level and high-level waste standards analyses at 10,000 years. Although EPA's uranium fuel cycle standards calculated doses over a period of 100 years, that choice was precedent-setting when those standards were published in 1977, and choice of a longer period would not have changed the regulatory outcome.

Both agencies tend to truncate their consideration of maximum exposed individuals in risk assessments similarly. The relevant distance used in an analysis is predicated by the scenario(s) selected; the time period for analysis of individual dose is generally 1,000 years (except for EPA's low-level and high-level waste standards, as mentioned above). This truncation is done for computational efficiency, and the period is chosen so that the doses after truncation are well below those of interest for limiting individual dose.

## 2.2 Differences

In general, in the process of setting generic standards, only a few minor differences exist between EPA and NRC dose/risk assessment methods; however, some differences in determining risk and exposures can occur when the agencies more precisely estimate dose/risk on a cancer site basis.

**Different methods for calculating risk are used.**

EPA and NRC use different detailed methods for calculating risks due to radionuclide intakes and exposures. In many cases, the agencies have used a nominal dose/risk conversion factor to calculate risk from both external and internal exposures to radiation. Both agencies currently use biokinetic models based on ICRP Publication 30, and similar risk-per-unit-dose

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<sup>13</sup> As of December 20, 1993, 58 FR 66398, 40 CFR Part 191 no longer applies to NRC's high-level waste program for Yucca Mountain. A standard for Yucca Mountain awaits the recommendations of the National Academy of Sciences on the issue of truncation in accordance with provisions of Section 801 of the Energy Policy Act of 1992.

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values for uniform whole-body, low-linear energy transfer (LET) radiation (approximately  $5 \times 10^{-2} \text{ Sv}^{-1}$ ); however, differences in methodology can often result in risk estimates that differ by a factor of 2, and in a few cases, for specific nuclides, by much more. The essential differences are summarized as follows:

1. Decay product ingrowth model. NRC uses the ICRP Publication 30 ingrowth model, which assumes that almost all decay products (often with different chemical behavior) in tissues are retained exactly as would be the original intake radionuclide. This approach is embodied in EPA's Federal Guidance Report No. 11. For most radionuclides, EPA's ingrowth model in calculations since 1988 assumes that decay products arising in tissues are redistributed and retained according to their own retention models.
2. Age-specific dose rates versus dose commitments. EPA calculates the risk of each type of cancer location based on age-specific dose rates and age-specific cancer radiation risks. These risks are age-averaged, using US life-table data. NRC risks are usually calculated using the product of 50-year dose commitments for a "reference man," and a nominal risk per unit dose.
3. Absorbed dose versus dose equivalent. The dose equivalent concept used in NRC dose calculations assumes that the relative biological effectiveness (RBE) of alpha radiation is always 20 times that of low-LET radiation. In recent assessments, EPA has used an alpha radiation RBE of 1.1 for leukemia, and 8 for all other alpha-radiation-induced cancer risks<sup>14</sup>.
4. Cancer site-specific dose versus effective dose equivalent. The effective dose equivalent used by NRC, which is based on BEIR V and ICRP Publication 30, is a weighted average of the dose equivalent in certain tissues. The implied risk of fatal bone cancer, by NRC's formulation, is slightly smaller than that used by EPA. It also incorporates a substantial weight for gonadal doses that are related to genetic risk, but not cancer risk.

For short-lived low LET-emitting radionuclides that are nearly uniformly distributed in the body, the differences between NRC and EPA estimates, because of the above factors, are

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<sup>14</sup> This converts BEIR III risks per rad of low LET radiation into risks per rad of high LET radiation.

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small. In other cases, especially those of long-lived bone-seeking alpha emitters, NRC's risk estimates can exceed EPA's by a factor of 5 or more<sup>15</sup>.

However, NRC allows different approaches for estimating risks from exposure under specific circumstances. For example, for evaluation of actual accidents involving known individuals or where a more precise evaluation is desired, NRC uses age- and organ-specific risk factors. On the other hand, for rulemaking or development of measures to prevent or control exposures, an approach that assesses dose and uses a nominal dose/risk conversion factor is considered appropriate, because planning and design normally include conservatisms and include large safety factors<sup>16</sup>.

**Different exposure scenarios are used in some programs.**

Earlier discussions (Section 2.1) stated that EPA and NRC generally draw from the same group of exposure scenarios for their analyses. However, scenarios used by each agency show some differences. The most important is that for assessments involving radioactive waste disposal (other than uranium mill tailings), the agencies routinely assume individuals will intrude into the waste at some point in the future, whereas EPA does not generally assume intrusion in solid waste programs (municipal waste disposal, hazardous waste disposal, and site remediation in some cases). Consequently, the risk assessment approaches differ, which in turn drives the development of requirements and site assessments. For radioactive waste sites, EPA and NRC require that disposal facilities are designed, constructed, and closed in a manner that ensures protection of inadvertent intruders. In EPA's solid waste programs, however, significant credit is assumed for institutional controls (e.g., deed restrictions, well permits) to restrict access to sites and prevent intrusion.

Exposure scenarios also differ in terms of the assumed duration of human exposure to the hazard. Although NRC programs generally assume a 50- or 70-year exposure, and most EPA radiation programs assume a 70-year (lifetime) exposure for a maximum exposed individual, the EPA Superfund program typically uses a 30-year exposure period. However, Superfund uses cancer incidence, not cancer fatality, as its risk indicator, so the net effect on the numerically-assessed health risk measure is small. In addition, EPA is currently

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<sup>15</sup> Although EPA is currently in the process of revising its risk calculations, most of these differences will remain. New organ-specific risk models are based largely on more recent assessments of the Japanese atomic bomb survivors. The new BEIR V average whole-body low LET radiation risk is about  $5 \times 10^{-4}$  Sv<sup>-1</sup> for low-dose, low-dose rate conditions. The alpha-radiation RBE is 1, 10, and 20 for leukemia, breast cancer, and all other cancers, respectively. Other changes include re-weighting the regional doses used for calculating lung and colon cancer risks and estimating the risk of skin cancer.

<sup>16</sup> See NUREG/CR-4214, Revision 1, Part II, Addendums 1 and 2, "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis," regarding the estimation of low and high LET health effects.

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evaluating the distribution of risk with age, which may further reduce the significance of differences in exposure duration.

In deriving the concentration values listed in Appendix B, 10 CFR Part 20, that are provided to facilitate demonstrations of compliance with the dose limits for members of the public, NRC considered only direct continuous ingestion or inhalation of effluents at the boundary of the restricted area. Because of these conservative exposure pathway assumptions, no reconcentration or food pathways were considered. EPA's NESHAPS regulations (40 CFR Part 61) allow compliance demonstrations for the maximum exposed actual individual, and, therefore, consider additional exposure pathways from airborne releases (e.g., ground deposition) that, for certain nuclides and specific scenarios, could be important to the potential doses received by these individuals. Although, within the range of application of the NRC effluent release values, the difference in assessed dose to an individual may not be significant, the scenarios addressed by EPA are more extensive.

**Truncation with distance or magnitude of dose affects consideration of population doses.**

EPA usually assesses population risk without truncation in distance. For example, EPA's high-level waste standards, fuel cycle standards, and uranium mill tailings standards all considered global population doses. In contrast, one EPA program, NESHAPS, did truncate its assessments in distance (100 km), using the precedent set for chemical contaminants, but made the judgment that the regulatory outcome would not be affected by that decision. NRC generally truncates estimation of population doses in terms of distance. The technical basis for this is that, beyond a certain distance, the uncertainties in both the data and models can undermine the reliability of the calculated results at very low dose levels. Many programs either implicitly (via choice of scenarios) or explicitly determine a distance beyond which doses and affected populations are not considered.

Truncation based on magnitude of dose is not carried out by EPA because it is inconsistent with the linear, no-threshold dose-response assumption (i.e., it would ignore the cumulative population risk below the truncation threshold). In 1990, NRC issued a "Below Regulatory Concern" (BRC) policy statement that allowed for truncating very small doses, on the basis of magnitude, when calculating collective exposures. However, in response to public concern about the implications of such a policy, NRC placed a moratorium on the BRC concept the following year, and, after Congressional revocation, formally withdrew the BRC policy in 1993.

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### **3.0 RISK MANAGEMENT**

*Risk management* encompasses the value judgments and pragmatic tradeoffs made by regulators who must make policy decisions in the face of different statutory mandates, imperfect information, limited resources (both of the regulator and of the entity responsible for creating the risk situation), institutional precedents, and other limitations.

For this part of the review, the risk management programs from both agencies were examined and the preliminary results are summarized in the appendix, Table 2, "Risk Management Comparison Chart" (under development).

Each program was characterized according to the following program elements:

- |                         |  |
|-------------------------|--|
| ● risk scope:           | dose, health risk; population dose, health detriment; exposure probability |
| ● risk/dose objective:  | objective sought under program   |
| ● basis for objective:  | policy or other factors considered in selecting the objective              |
| ● implementation:       | regulatory mechanisms to achieve objective                                 |
| ● compliance:           | method for determining compliance with regulations                         |
| ● exceptions:           | basis for granting exceptions to the objective                             |
| ● uncertainty measures: | method for addressing uncertainties in compliance                          |

#### 3.1 Similarities

**Similar levels of protection, despite fundamental differences in approaches.**

Although the two agencies differ conceptually in their approaches to risk and dose limits or objectives (see the discussion below), EPA and NRC programs often achieve similar levels of protection. The apparent difference between the risk implied by NRC's dose limit and EPA's risk objective ( $10^{-4}$  vs  $3.5 \times 10^{-3}$ ) can be misleading, because the application of ALARA for NRC licensees almost always results in significant reductions in actual risk levels. On the other hand, most EPA hazardous material standards permit risks slightly higher than the risk objective, when justified, based on feasibility considerations. In addition, EPA has recently been considering establishing a threshold based on  $10^{-3}$  lifetime risk to distinguish between wastes that need to be controlled as hazardous waste versus those that can be controlled as solid waste through the agency's Hazardous Waste Identification Rulemaking. Despite this similarity in achieved levels of protection, NRC's radiation protection programs are perceived as less protective than EPA's, when the focus is limited to a comparison between numerical EPA goals and NRC limits (see discussion under Section 3.2, "Differences"). Although not directly comparable, EPA's indoor radon program

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provides guidance for remedial action by property owners at risk levels on the order of  $10^{-2}$ , but this is not a regulatory program in the licensing/permitting sense, and significantly lower risks are difficult and costly to achieve.

**Risk/Dose Limits Applicable to Occupational and Public Exposure.**

Both the EPA and NRC use the same risk/dose limits in their approaches for providing radiation protection for workers and the public. These limits are contained in existing and proposed Federal radiation protection guidance documents approved by the President<sup>17</sup>. For the general public, the proposed recommendation is that the combined radiation dose incurred in any single year from all sources of exposure covered by the recommendations should not normally exceed a Radiation Protection Guide of 1 mSv (100 mrem) effective dose equivalent to an individual. If this guidance dose value was to be received continuously over 70 years, the projected lifetime risk is numerically 10 to 100 times higher than the risk goals applied to remedial actions involving non-radiological carcinogens.

**Use of ICRP and NCRP recommendations.**

The radiation risk/dose limits and source constraints of both agencies are generally compatible with the recommendations of the recognized national and international organizations. NRC cites ICRP and NCRP recommendations as the "part of" the basis for its regulations, and EPA, although it does not cite them as a basis, considers these recommendations. EPA does not officially conform to ICRP recommendations; however, its standards are generally consistent with them. An area of inconsistency is that ALARA (i.e., optimization of protection) is not a part of many EPA regulations. NRC standards are generally consistent with the ICRP recommendations. However, NRC does not, in every case, separately impose source constraints at a fraction of the public dose limit. NRC has, however, referenced EPA's generally applicable environmental standards (e.g., 40 CFR Part 190) in its regulations and has included the requirement that procedures and engineering controls be used to attain ALARA doses<sup>18</sup>.

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<sup>17</sup> See "Radiation Protection Guidance to Federal Agencies for Occupational Exposure" dated January 1987. Similar guidance applicable to the general public is expected to be issued by EPA soon.

<sup>18</sup> The recent revision to 10 CFR Part 20 requires licensee radiation protection programs to implement procedures and controls designed to ensure that releases and doses are ALARA.

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**Similar array of decision mechanisms to demonstrate compliance.**

EPA and NRC rely on modeling, monitoring, or design to determine whether compliance has been achieved. Compliance requirements often include modeling or design specifications. Monitoring is frequently used by both agencies, to ensure that compliance goals are achieved.

### 3.2 Differences

**Different primary risk management approaches.**

NRC and EPA use fundamentally different risk management approaches. In protecting individual members of the public, NRC imposes a dose limit with an implied risk of  $5 \times 10^{-5}$  risk/year, or about  $4 \times 10^{-5}$  lifetime<sup>19</sup>, and then applies the ALARA concept below this limit. ALARA is usually **applied on a site-specific basis**, but has been applied generically in assessments supporting rulemaking activities. The projected facility-specific risk can vary as a function of the ALARA process, because this process takes into account the state of technology, the economics of improvements, and other societal and socioeconomic considerations. NRC does not, in general, generically exempt licensees from the provisions in its regulations.

EPA uses a **fixed upper bound risk objective** (approximately  $1 \times 10^{-4}$  lifetime), and considers further risk reduction if it is justified by cost/benefit considerations. In cases where EPA determines that there would be clearly unbearable economic costs or excessive environmental consequences, EPA will allow higher calculated risks through exercise of enforcement discretion or compliance agreements. EPA radiation standards are usually derived and **applied generically to classes of sources**, and usually contain provisions for exceptions (which, however, are rarely used).

**Different compliance approaches for controlling actual public exposures.**

In providing means for demonstrating compliance with its public exposure limits, NRC frequently uses tables of concentrations or quantities that have been derived through conservative generic assessments. EPA has, in cases, provided specific assessment methods that can be used to demonstrate compliance on a case-by-case basis. As indicated previously, NRC regulations include explicit concentration limits for the air and water pathways for demonstrating compliance with its public dose limits (e.g., Appendix B to 10 CFR Part 20).

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<sup>19</sup> When expressed as a dose limit, this is 100 mrem/year (1 mSv/year) for 70 years.

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The concentrations represent values that, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 50 mrem (0.5mSv). These concentration limits can be applied at the site boundary, but the values are frequently applied at the point of discharge. Although actual doses, to real individuals, from airborne effluents, have typically been shown not to exceed EPA's CAA dose criterion of 10 mrem (0.1mSv)/year, disagreements have arisen on the sufficiency of the NRC compliance approach.

**Generic vs. site-specific focus and use of regulatory guidance.**

A fundamental difference in approach, reflected in a number of programs, is that NRC's mandate and licensing authority frequently focus on regulation on a site-by-site basis under the "umbrella" of basic dose limits. EPA, in its primary role for radiological risks, as a standards-setting (rather than licensing) agency, tends to regulate by class of facility or source, pollutant, or pathway (a "generic" approach). However, EPA also regulates individual facilities in those programs where Congress has granted implementation authority (e.g., RCRA, Clean Water Act, and SDWA).

Because NRC regulations usually specify either site-specific license requirements based upon ALARA (e.g., at reactors and fuel cycle facilities) or a dose limit coupled with a general ALARA requirement (e.g., for materials licensees), NRC makes extensive use of regulatory guidance (generic guides, technical positions) in assisting licensees to achieve its dose (risk)-limiting objectives. The reliance on regulatory guidance offers licensees flexibility in deciding how best to satisfy NRC requirements. NRC does issue generic regulations for classes or types of licensees and has incorporated EPA standards in its regulations (e.g., 40 CFR Part 190, the uranium fuel cycle standard).

Where EPA is responsible for setting generic radiological source standards, risk objectives are generally achieved by regulations directly, and do not depend on use of regulatory guidance. In programs like Superfund, where EPA does address specific sites, guidance is available that provides for some flexibility comparable to NRC guidance in achieving specified risk goals.

**Use of risk or dose as the risk reduction objective.**

NRC has traditionally used radiological dose as the endpoint for rulemaking and compliance assessment. That is, most regulatory decisions are related to the acceptability of dose as a surrogate for risk. The ICRP dose limits (adopted by NRC) reflect ICRP recommendations for acceptable risk selections for radiation workers and for the public. In all recent rulemakings, NRC has made explicit estimates of the relationship between risk and dose.

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In contrast, EPA programs have generally used health risk as the basis for rulemakings and policies, and most use dose only as a measure of compliance. However, the risks quantified have varied somewhat, depending on the regulation<sup>20</sup>. For example, cleanup decisions under Superfund are based on cancer incidence rather than fatalities; the risk factor for incidence is about 150 percent of that for fatalities. An exception to EPA's primary reliance on risk as a basis for standard setting can be found in its development of the containment requirements of 40 CFR Part 191. The defined release limits were derived from EPA's judgment of what hypothetical repositories could achieve, although comparisons were made to the risks attendant to natural ore bodies. Under the Energy Policy Act of 1992, EPA is obligated to promulgate health-based standards for a proposed repository at Yucca Mountain following recommendations of the National Academy of Sciences. NRC will then conform its regulations to final EPA standards.

#### **Uses of population risk.**

EPA standards almost always include individual dose limits, but population risk may lead to additional regulations requiring more control than that required to satisfy individual dose limits. Examples are limits on quantities of specified long-lived radioisotopes released from high-level waste repositories under 40 CFR Part 191, and of Kr-85, I-129, Pu-239, and other  $\alpha$ -emitting transuranics from uranium fuel cycle facilities, under 40 CFR Part 190.

NRC does not specify numerical requirements specifically based on collective risk in populations, but either generally limits public exposure through individual dose limits or incorporation of EPA standards into its regulations. Consideration of population risk can affect the choice of individual dose limits in NRC programs. Examples include: ALARA assessments for effluents, National Environmental Policy Act (NEPA) assessments, consumer product design and distribution, and backfitting reviews.

#### **Explicit disagreements on risk objectives.**

There are a number of areas in which NRC and EPA programs, which apply to the same sources, specify or imply different numerical levels of risk for protection of the public. These differences are usually based on the different regulatory approaches used by the agencies.

For example, groundwater protection in EPA's draft low-level waste standards is specified at the level of drinking water standards (4 mrem/year (0.04 mSv/yr); about a  $10^{-4}$  lifetime risk).

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<sup>20</sup> See "Issues Paper on Radiation Site Cleanup Regulations," EPA 402-R-93-084, September 1993.

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as is the policy for all other EPA groundwater protection programs<sup>21</sup>, but is absent, as specific limits, in NRC regulations for low-level wastes<sup>22</sup>. NRC limits the combined hazard from all pathways (except direct radiation) to an implied lifetime risk level of about  $10^{-3}$ , or 25 mrem/year (0.25 mSv /year) whole body dose, but does not specify separate limits for doses resulting from transport of radionuclides in groundwater.

As another example of numerical differences in the standards established by the agencies, NRC's radiation protection standards require that air emissions, when combined with the doses from all other pathways, meet the 100 mrem/year (1 mSv/year) public dose limit and that procedures and design controls limit releases and doses to ALARA. In contrast, EPA standards under the CAA limit the dose from air emissions to 10 mrem/year (0.1 mSv/year) and no more than 3 mrem/year (0.03 mSv/year) for radioiodine.

#### **4.0 CONCLUSIONS AND FINDINGS**

The examination of programs in the two agencies demonstrated that, despite differences in the history and regulatory approaches of the two agencies, they often achieve comparable results in their regulatory programs, and are currently embarked on paths that should reduce remaining differences. The remaining differences are discussed below.

##### 4.1 Risk Assessment

Although the two agencies carry out risk assessment from different viewpoints, they commonly arrive at similar outcomes. That is, if EPA and NRC were to assess a defined environmental hazard, the two agencies would likely calculate a similar level of implied risk. Nonetheless, differences were found in some program areas. They are:

- Different methods are used for calculating risk for certain nuclides, and, in many programs, committed effective dose equivalents are converted to risk, using a single dose-to-risk conversion factor (i.e., organ risk conversion factors are not always used).
- Different biological endpoints (i.e., cancer incidence and mortality) are used to numerically quantify risk.

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<sup>21</sup> See "Protecting The Nation's Groundwater: EPA's Strategy for the 1990s," July 1991.

<sup>22</sup> This may reflect the fact that EPA's primary responsibility is protection of the environment per

se (i.e., water as a resource), whereas NRC's primary responsibility is to ensure adequate and consistent protection of public health and safety in the use of nuclear materials.

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- Different pathway parameters (e.g., intruder protection, presumed exposure times) are sometimes used.
- Truncation of population dose analyses is performed differently.

The comparison of risk assessment approaches has helped the agencies gain a better understanding of each other's internal practices and procedures for estimating doses and risks associated with radiation in the environment. Although resolution of these differences in risk assessment approaches is unlikely to significantly affect the outcome of agency regulatory decisions, unresolved differences can affect public perception of the scientific credibility of the two agencies.

#### 4.2 Risk Management

The two agencies have traditionally used fundamentally different approaches to regulation as exemplified by the following:

- EPA establishes generic standards by pathway or class of source; NRC has established dose limits for all pathways combined, and requires universal application of the ALARA principle.
- The internationally-accepted annual dose limit for a member of the public used by NRC implies an upper bound lifetime (70 years) risk of about  $4 \times 10^{-3}$  for individual sources with the application of the ALARA principle typically reducing actual exposures to risk levels on the order of  $1 \times 10^{-5}$  lifetime; EPA generally promotes a risk goal of  $10^{-6}$ , and uses a risk constraint of about  $1 \times 10^{-4}$  for specific sources or exposure pathways, with practicality of achieving that level factored into site-specific cases.
- EPA satisfies the ICRP recommendation to constrain emissions from classes of sources to less than the individual dose limit; many NRC programs do not independently impose such constraints (although ALARA is always applied), while others rely on reference to relevant EPA standards for particular classes of sources.
- NRC programs use dose limits and ALARA, whereas EPA programs frequently use a single risk objective or range as the regulatory endpoint.
- EPA standards frequently limit population risk directly; NRC programs are generally more focused upon risk to individuals.

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- Explicit risk objectives may differ between EPA and NRC by up to several orders of magnitude.



Tennessee Valley Authority, 400 West Summit Hill Drive, Knoxville, Tennessee 37902-1499

Craven Crowell  
Chairman, Board of Directors

January 27, 1995

The Honorable George E. Brown, Jr.  
Ranking Democratic Member  
Committee on Science  
U.S. House of Representatives  
Washington, DC 20515

Dear Mr. Brown:

Thank you for your letter concerning TVA's comments on Title III of H.R. 9. The provisions of H.R. 9 would establish requirements for the conduct of risk assessments and the communication of risk assessment results to the public, which could have a mixed effect on TVA.

The focus of Title III of the legislation appears to be on regulatory programs in the public health, safety, or environmental areas. TVA has no such regulatory programs. However, TVA does regulate the placement of dams or other facilities in and along the Tennessee River system under Section 26a of the TVA Act. As required by the National Environmental Policy Act (NEPA), TVA does conduct environmental reviews in connection with requests for approval of river-use facilities under Section 26a. Under the Title III broad definition of risk assessment, these NEPA reviews might be viewed as the kind of risk assessments which would be subject to the new requirements. If this is the case, the costs of such reviews would increase, and they would likely take longer to complete. Because we have little experience with the type of formal risk assessment that would be required by Title III, we do not have a basis for estimating how much costs might increase or how long such assessments would take to complete.

In addition, TVA is required to provide risk-assessment types of information to the Nuclear Regulatory Commission in connection with the regulation of TVA's nuclear units. Under Section 112(r) of the Clean Air Act, TVA may also be required to provide hazard assessments for some of its facilities. Although EPA has not promulgated the final rules for such hazard assessments, H.R. 9's definition of risk assessment appears broad enough to encompass such assessments. Again, TVA's costs in conducting such assessments would likely increase, but we are unable to estimate by how much.

The Honorable George E. Brown, Jr.

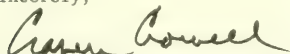
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Unlike most other federal agencies, TVA also carries out a wide range of business activities that are regulated under the same public health, safety, and environmental programs that apply to private businesses. In that regard, we agree that regulatory risk assessments that are based on sound scientific principles and that are communicated in a more understandable manner to the public should foster better regulation. As a business entity that must compete in today's competitive world, TVA fully appreciates the importance of well-considered regulations.

We appreciate the opportunity to share our views on Title III of H.R. 9.

Sincerely,



Craven Crowell

cc: The Honorable Robert S. Walker  
Chairman  
Committee on Science  
U.S. House of Representatives  
Washington, DC 20515



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

JAN 30 1995

The Honorable George E. Brown, Jr.  
Ranking Democratic Member  
Committee on Science  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Brown:

This responds to your request for the views of the Department of Health and Human Services (HHS) on portions of H.R. 9, the "Job Creation and Wage Enhancement Act of 1995".

Since your incoming letter asked only about the effects of titles III and VII of H.R. 9 on this Department's programs, we have limited the scope of this response to those titles. However, we take this opportunity to note that we also have serious concerns with other titles of the bill.

In General

In summary, we are deeply concerned by the potential for harm to HHS programs, and to the public interest, created by many provisions of H.R. 9, including titles III and VII.

At the outset, we would stress that we share the President's commitment to eliminating unnecessary regulations and minimizing regulatory burdens. And we are fully in agreement with the principles concerning Federal regulation that have been espoused by the Administration and embodied in Executive Order 12866. These principles include a recognition of the value of tools such as risk assessment, cost-benefit analysis, and peer review in assisting agencies to make informed and balanced judgments concerning the need for and impact of particular rules and enforcement actions.

We also strongly agree with the statements, in the findings and purposes provisions of title III of H.R. 9, that "public and private resources available to address health and safety concerns are not unlimited; those resources need to be allocated to

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address the greatest needs in the most cost-effective manner"; that "regulatory priorities should be based on realistic consideration of risk"; and that "the priority setting process must include...risk management choices that are grounded in cost-benefit principles." (§§ 3001, 3102.) We fully agree with the goal of making the regulatory process more responsive and more streamlined.

Unfortunately, H.R. 9 fails to meet its own standards for responsible rulemaking. Rather than eliminating obstacles to more streamlined, cost-effective regulatory actions, titles III and VII would add numerous burdensome and unproductive procedural requirements that would greatly increase the costs and delays of the regulatory process. If these provisions were enacted, HHS could not meet its statutory obligations at our current staffing levels, let alone after the substantial reductions in personnel projected for the coming years. These delays would impose a variety of costs and burdens on the private sector, including economic losses and risks to the public health. (In addition, H.R. 9 falls short of its own "standard of clarity" (§7006), containing ambiguities, undefined terms, and the like, so that we cannot clearly ascertain the intent or effect of numerous provisions. Were the bill to be enacted in its present form, those flaws alone would produce considerable delay, confusion, waste, and litigation.)

A fundamental weakness of the approach taken in titles III and VII is that they attack perceived problems of over-regulation at the wrong point, and apply simplistic "one size fits all" solutions. HHS and other Federal agencies do not regulate in a vacuum, but pursuant to the dictates of specific statutory mandates enacted by the Congress. If our legislators conclude that certain laws are too prescriptive, the appropriate course is to amend or repeal the offending laws. Instead, titles III and VII leave in place the statutory requirements (and timetables) for implementing regulations, but vastly increase the difficulty of promulgating those regulations and enforcing the law.

#### Description of Provisions of Titles III and VII

Title III would add requirements for risk assessment, cost/benefit analyses, and peer review applicable only to regulatory activities under Federal programs designed to protect human health, safety, or the environment. With respect to HHS programs, title III would have a major impact on the activities of the Food and Drug Administration (FDA). Depending on what is meant by the term "Federal regulatory program", these provisions could have limited application also to certain other HHS programs, including Medicare and Medicaid.

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The "risk assessment" provisions of title III-A would require use of a single approach, whose elements are specified in detail, in any case where the magnitude of a risk must be quantified or estimated in order to take a regulatory action. Unlike other provisions of the bill, this requirement is not limited to agency actions whose impact will exceed a given threshold, but applies across the board.

Title III-B requires development and publication, for each proposed and final rule having an annual effect on the economy of \$25,000,000 or more, of an analysis of risk reduction or other benefits and costs (including direct and indirect costs to Federal, State, and local government and the private sector), together with enumerated certifications as to the rule's necessity and reasonableness, including a certification that the benefits of the rule will justify the costs.

Title III-C requires peer review of certain risk assessments and cost/benefit analyses, although the language is so confused that the scope of the requirement is unclear. We believe peer review would be required for risk assessments and cost/benefit analyses in connection with a rule having an impact of \$100,000,000; the requirement may also be intended to apply to any cost/benefit analysis of a rule costing \$25,000,000 or more.

Title VII imposes further requirements applicable to all Federal rulemaking. This title would require Regulatory Impact Analyses (RIAs) for virtually all regulations, by making the requirement applicable to any rule affecting more than 100 persons or costing any one person \$1,000,000 to comply (under the Reagan and Clinton Executive Orders in effect since 1981, the threshold is \$100,000,000). It would require publication of a "notice of intent", together with an abbreviated RIA, 90 days before publication of a Notice of Proposed Rulemaking, for virtually every Federal regulation. It would require that a hearing be held whenever more than 100 interested persons commented on any rule proposed by the agency. And it would dictate many details of the Executive Branch's internal management of the rulemaking process, by enacting into law President Reagan's Executive Order 12291. This will severely restrict the ability of this and future Presidents to manage key activities of the Executive Branch.

#### Impact on HHS Programs

Many of the specific activities or procedures required by titles III and VII are invaluable regulatory tools when used appropriately, in circumstances where they can assist in the task of producing informed, responsive, and responsible regulatory rules and decisions as efficiently and economically as possible.

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But H.R. 9 requires use of these tools in many circumstances where they cannot make a productive contribution to the decision-making process, but will at best add cost and delays that burden both government and the regulated sectors, and at worst will add unnecessary confusion by introducing irrelevant considerations.

#### Risk Assessment

FDA must perform tens of thousands of risk assessments annually. The circumstances calling for risk assessment range from matters such as applications for new human drug approvals (where a scientifically rigorous assessment is appropriate), to determinations of whether signs of rodent infestation in a warehouse render food stored there adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (where a determination fully adequate to meet the requirements of the Act can be made by a much simpler procedure, and delay would impose substantial and unnecessary economic losses on the regulated industry). The choice of risk assessment method, and the determination whether the assessment should be subjected to peer review, should be made on the basis of what those procedures can be expected to contribute to the decisionmaking process. The "one size fits all" approach of title III would require exhaustive risk analysis procedures, and peer reviews, in many cases where such procedures could only be counterproductive.

#### Cost/Benefit Analyses

H.R. 9 would also enormously expand requirements for cost/benefit analyses. Under the Executive Orders in effect since 1981, such analyses are part of the Regulatory Impact Analysis required to be transmitted to the Office of Management and Budget for each rule promulgated by an agency with an annual impact of \$100,000,000. These analyses require considerable agency resources to prepare. The cost assessments included in RIAs are of limited usefulness when (as is often the case) adequate and reliable data on cost impacts on local government and the private sector are unavailable. The burdens and difficulties of RIAs are limited under current procedures, however, because they are restricted to those relatively few cases where the effort is clearly justified by the magnitude of the impact, and the cost analyses are only used as a tool to guide the internal review of the proposed rule.

Under H.R. 9, in contrast, cost/benefit analysis would be required for a far larger number of regulations (FDA estimates that a significant number of its rules would come under the \$25,000,000 threshold, compared to an average of 4 a year under current rules). Analyses accompanying some rules would also be subject to peer review. These requirements would be applied even

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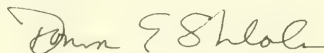
where, as is the case with the food and drug laws, cost impact is not a factor which may even be considered under the statutory mandate to protect the public from adulterated and misbranded products.

Given the likelihood that adequate data will be unavailable, and the fact that there is no general agreement on the appropriate techniques for estimating economic impact equivalent to the consensus on the scientific methods to be used to assess impacts on human health, we would expect the economic peer review process to produce many disagreements with agency conclusions leading to further discussions and delay.

In conclusion, for the reasons detailed above, we strongly object to the provisions we have discussed above.

Enclosed with this letter are answers to specific questions raised by Rep. Brown, which provide details casting further light on the concerns stated above.

Sincerely,

A handwritten signature in dark ink, appearing to read "John F. Shole". The signature is fluid and cursive, with the first name "John" and last name "Shole" clearly distinguishable.

Secretary

Enclosure

# QUESTIONS

1. Please identify the programs in the Department which would be subject to the requirements of the Risk Assessment and Communication Act of 1995 (Title III of H.R. 9), taking into account Title VII and other relevant sections of H.R. 9.

Many of the FDA's actions under virtually every statute it implements would be subject to the requirements of Title III of H.R. 9. The FDA's primary authority is the Federal Food, Drug, and Cosmetic Act (FD&C Act), which, among other things, prohibits the introduction into interstate commerce of any food, drug, medical device or cosmetic that is adulterated, misbranded, counterfeit, or that does not have the necessary pre-marketing approvals. The FDA also regulates the quality, sale, and distribution of biological products (e.g., blood and vaccines) through the Public Health Service Act. The FDA accomplishes these missions through a variety of regulatory mechanisms and programs. These include pre-market approval of drugs, medical devices, biologicals, food additives and color additives; post-market surveillance and reporting for regulated products; inspection of the locations where all regulated products are manufactured or held; and inspection of products that are offered for import into the United States.

All of the FDA's programs may be affected by H.R. 9. However, the true scope of the impact of H.R. 9 is difficult to gauge because of our uncertainty as to its scope. For example, Subpart A of Title III does not appear to be limited to risk assessments in connection with rulemaking, but would appear to apply to risk assessments made in connection with all actions (e.g., enforcement actions) under a regulatory program. Nor is the requirement limited to those risk assessments with significant impact (e.g., cost above a threshold amount), as is the case with some other provisions of the bill.

In addition to FDA, the bill's provisions appear to apply to some activities conducted by other PHS agencies (Centers for Disease Control, Agency for Health Care Policy and Research) and HCFA. Under the Clinical Laboratories Improvement Amendments of 1988 and a number of provisions of the Social Security Act, HCFA regulates the safety of laboratories, nursing homes, hospitals, and other institutions. CDC, primarily through NIOSH, conducts scientific assessments of occupational safety and health risks, as well as other risks related to AIDS and health care practices (e.g., nosocomial or in-hospital infections). Finally, the AHCPR conducts risk assessments in evaluating the cost-effectiveness of medical technology.

2. Using the definitions of "risk assessment" and "risk characterizations" set out in section 3107 of the Act, how

many risk assessments and risk characterizations were prepared by, or on behalf of, the programs in the Department over the last fiscal year? Of those, how many would be considered to be a "screening analysis" exempted under Section 3103(b)(2)?

Tens of thousands of risk assessments are done each year to address health and safety concerns. For example, for one part of FDA alone, the medical devices and radiation-emitting products group, the types and annual numbers of regulatory actions to which Title III might apply are as follows: 9,000 pre-market notifications; 400 pre-market approval applications and supplements; 1,400 product recalls; 5 safety alerts; and 12 device reclassification, among others. Similar numbers are repeated across the FDA for human drugs, biologicals, veterinary drugs, human foods, animal feed, food additives, and color additives.

In addition, for FY 94 the FDA took 186,724 industry surveillance actions, of which 29,459 resulted in import detentions, another 7,380 resulted in adverse findings, 3,247 resulted in recalls, and 122 resulted in civil or criminal enforcement actions brought in Federal courts. The determination as to what course of action is appropriate following an FDA inspection showing that the law has been violated is, in part, based on a risk assessment. That risk assessment takes into consideration factors such as the nature, scope, and potential impact of the alleged violations.

Very few of FDA's risk assessments would be considered to be a "screening analysis" exempted under Section 3103(b)(2). Although the exemption under Section 3103(b)(2)(A)(ii) can be read to exempt product approval, Section 3103(b)(2)(B)(i) would exclude from that exemption any analyses that are used to impose restrictions on substances or activities.

3. Please describe the Department's present practices, including references to any published guidelines or procedures, relating to risk assessment, risk characterization, cost-benefit analysis, or peer review.

Risk Assessment/Risk Characterization: FDA was perhaps the first federal agency to use risk assessment for purposes of regulatory decision-making. FDA had statutory requirements to make decisions about risks, and for over 20 years has used risk assessment as a means of making decisions about carcinogenic agents in the food supply.

FDA recognizes risk assessment as an important analytical tool. It is, however, only one source of input to public-health policy and decision-making. Such decisions necessarily

consider not only the technical, scientific data that are analyzed and summarized in a risk assessment, but also such issues as the availability of products to the public, and the unavoidability of the hazard (in the case of food contaminants).

FDA takes many regulatory actions incorporating risk assessment --including enforcement actions, safety alerts, product approvals, recalls, and major post-market safety reviews, among others--to attack the broad range of public health threats within its jurisdiction. For a few of the more important regulatory initiatives, such as major regulations, FDA engages in detailed and extensive risk assessments. In most instances, the risk assessments can be accomplished by a less intricate approach that is both fully adequate for the circumstances and much more expeditious. The unjustified delay introduced in such situations by unnecessarily detailed analyses would cause unacceptable or unnecessary economic or public health costs.

Often, the risks FDA faces are already known or well-established (e.g., the risk to human health from toxicants such as botulism, listeria, salmonella, or excess doses of elemental iron). In such cases, a formal risk assessment would be unnecessary. In other circumstances, as a product is offered for import that appears to violate the FD&C Act, so little is known about the product that a formal risk assessment could not be done. At present, in those circumstances, the importer must marshal the evidence that the product meets U.S. law; the FDA is not required to gather evidence to prove that it does not. The requirement of doing a risk assessment would shift that burden back to the FDA, to the detriment of U.S. consumers.

The FDA publishes many manuals to assist its staff in doing their work, e.g., the Inspection Operations Manual Guide, Regulatory Procedures Manual, Compliance Policy Guides, and numerous guidelines on how to review pre-market approval applications.

Cost Benefit Analysis: All HHS agencies follow internal procedures described in the HHS Guideline for Regulatory Analyses. In addition, in preparing analyses, there is substantial reliance on the technical literature and on OMB's guidelines.

Peer Review: FDA uses numerous standing external-expert advisory committees to review data and obtain expert opinion and advice on product safety and effectiveness, and on broad scientific and policy issues. FDA has prepared a Policy and Guidance Handbook for FDA Advisory Committees on how to conduct advisory committee meetings, and a more concise version, the Committee Member Guide to FDA Advisory Committees to provide policy guidance to all FDA advisory committees. Other

agencies, notably AHCPR, rely heavily on peer review as well. FDA solicits new members for its advisory committees through Federal Register notices and also publishes in the Federal Register forthcoming meetings each month. The Federal Register publications are augmented with a hot line which conveys up-to-the-minute modifications to meetings on a daily basis. The FDA has a manual on how to conduct advisory committee meetings.

4. If enacted into law, how would the Act affect the Department's present practices as described in question 3? If compliance with the Act would require additional resources in carrying out such practices, please estimate the additional resources (in terms of dollars and personnel) that would be required to carry out the provisions of the Act.

Title III requires that whenever the FDA performs a risk assessment, it use a single type of "risk assessment" procedure that incorporates a specific set of factors. It would further require that all risk assessments be performed in accordance with certain principles requiring exhaustive review of all available and relevant scientific data, discussion of assumptions, inferences, and models used and alternatives rejected. There are exceptions to the requirement for emergencies and screening analyses and risk characterizations appearing on product labels.

As presently drafted, the mandate for performance of a single, formulaic, highly documented and quantitative risk assessment appears to be so broad that it is virtually impossible to estimate the amount of resources that would be required to carry out such practices.

Some examples may help to illustrate the potential impact of Title III on FDA's ability to implement statutory provisions. Whenever an inspection reveals conditions that may constitute a violation of the FD&C Act, the inspector completes a "Notice of Inspectional Observations" (Form 483). On this form, the inspector documents the observations that show potential violations of the law. Such potentially violative conditions could be anything from bird and rodent excreta in a food storage warehouse to lack of records in a drug production facility. The Form 483 and other evidence (e.g., samples) are reviewed in the FDA's district office by a compliance officer who assesses whether the evidence shows violations of the FD&C Act, and if so, considers action appropriate to address the problem.

With respect to the bird and rodent dropping situation, the FD&C Act defines as adulterated any food that has been "held under insanitary conditions . . . whereby it may have been

rendered injurious to health." There are no standards or regulations, however, which define with specificity how many bird and rodent droppings in a food warehouse are sufficient to establish that the food in question may have been rendered injurious to health. Such a case-by-case determination can only be made in light of all available information, including information about the nature of the food, whether it will be processed further before being sold, and whether the containers or packaging were actually broken. Moreover, a determination must be made quickly if the adulterated food is to be kept out of commerce. Were the FDA required to conduct a written risk assessment for each such finding or action, its enforcement/compliance resources would not only quickly be overwhelmed, but the delay in taking action would also mean the goods would be distributed to the consumer. The consumer protection goals of the statute could not be accomplished.

Another example concerns the good manufacturing practice requirements to ensure safety of the blood supply. Blood collection facilities must meet certain requirements of the regulations implementing the statutory provisions on good manufacturing practices and safe, pure, and potent products. For example, the facilities must provide "adequate" space for quarantining blood products that gave questionable results in testing for HIV or other infectious agents. The labeling operations must also be separated spatially from other operations in a way "adequate" to prevent mixups. After an inspection of a blood facility, FDA compliance officers decide whether the inspector's observations of the quarantine and labeling areas show violations of the law and, if so, what action should be taken. Each such decision must be made on a case-by-case basis and involves risk assessment. These situations about the space allocations in blood collection are not typically considered "emergency" situations, but may, nevertheless, have serious public health consequences. An extensive delay in decisionmaking in order to conduct an elaborate and detailed risk assessment could result in shipment of infectious blood or blood labeled with the wrong blood type.

Another example relates to the decisions the FDA makes about whether to detain imported products for inspection and analysis. At present, the FDA has the ability to inspect approximately 2 percent of all imports of regulated products. To maximize the efficient use of its inspection resources, the FDA uses an automatic detention mechanism. Of the 29,459 detentions made in FY 94, over 13,000 were under the FDA's automatic detention program. Under that program, when the FDA has reason to believe that a particular product or commodity is likely to be violative, it places that product on automatic detention. The importer of the product is then required to establish that the product complies with the FD&C Act. Products not on automatic detention are allowed to enter the

country unless the FDA establishes that they are violative. The decision whether to place a product on automatic detention is, again, made on a case-by-case basis depending on a variety of factors. Where there is a possible health risk, however, as with contaminated mushrooms or lead leaching pottery, delay in putting an automatic detention in place could well result in needless exposure to health risks.

5. How does the Department obtain the information it uses to prepare risk assessments, cost-benefit analysis, or risk characterizations? Does the Department rely in part upon the private sector in providing the information needed by the Department to conduct such assessments or analyses? If so, would the Act require the Department to obtain additional information from the private sector in order to comply with the Act's requirements?

In general, HHS must rely on the private sector to provide information needed to conduct risk assessments for industry initiated actions. For example, companies that submit petitions to FDA requesting the approval and listing of a food additive or color additive, the approval of a drug or device, or the amendment of some generally recognized as safe (GRAS) regulations, must submit data that will enable the FDA to determine whether to allow use of the substance/product. When risk assessments are conducted on rules, the information comes from a variety of sources, including the scientific literature, Agency-generated analyses, and private-sector databases and information, and contracted studies. For enforcement and compliance actions, HHS generally relies on information available to it through current and past inspections, laboratory analyses, or other generally-available scientific information about risks and hazards.

The FDA does not now perform cost-benefit analyses of food and color additive approvals, drug approvals, or other product approvals. Generally, the FD&C Act and PHS Act dictate consideration of whether the substance product is safe and/or effective for its intended use without reference to cost/benefit considerations. The data required to perform such cost-benefit analyses for an industry initiated action such as a product approval would have to be provided by industry.

For actions that are initiated by the FDA, for example, to control an environmental or other unavoidable contaminant in food (PCBs, aflatoxin, vomitoxin) for which there is no "sponsor," or an action to withdraw approval of a product (e.g., a drug or food additive), the burden would fall on the FDA to develop the cost-benefit data and analysis.

For most actions taken by FDA, the statute does not permit consideration of issues unrelated to safety, effectiveness, or

product quality concerns. Cost-benefits analyses involve additional concerns that are not determinative under the statutory public health protection mandates.

6. (A) Please identify the regulations expected to be proposed or promulgated in the next two years which would require a Regulatory Impact Analysis under Title VII, an analysis of risk reduction benefits and costs or a certification under Subtitle B of Section 3201, or a peer review under Section 3301. (B) What additional procedures would the Department be required to follow to issue such regulations if the Act were enacted into law? (C) Would the Act permit judicial review of Department actions beyond what is presently permitted under the Administrative Procedure Act? (D) Please estimate the additional time and resources that would be necessary to complete the expected rulemaking following the required procedures. (E) If the Department is subject to court-ordered or statutory deadlines for completion of any such regulations, can the Department comply with the Act and still meet such deadlines?

6.(A) Because the definition of what is a "major rule" which triggers the Regulatory Impact Analysis requirements of Title VII (see section 7004(b), or the analysis of Risk Reduction Benefits and Costs (see section 3201(c)(2)), and peer review (see section 3301(h)) of Title III, potentially all FDA rules slated for publication in the next two years would be affected. Some significant rules would include:

Iron Toxicity Prevention -- A regulation to protect children from accidental poisoning by iron supplements.

Bottled Water Standards -- Regulations to ensure that bottled water is free from pesticides, heavy metals, and other contaminants.

Seafood Safety -- A final regulation to enhance seafood safety through the use of industry-chosen, risk-based controls.

Mammography Standards -- Mandated by statute. Establishes standards for mammography clinics, including quality of films produced, training for clinic personnel, recordkeeping, equipment used, etc.

Adverse Reaction Reporting for Drugs -- Final rule to improve the reporting to FDA of serious and life-threatening reactions to drugs.

Medical Device User Facility Reporting -- Implements statutory mandate to have serious medical device failures (resulting in death or serious injury) reported to FDA.

Look Back Blood Good Manufacturing Practices -- A retrospective review to determine how FDA's blood regulations can be made less burdensome and otherwise modernized.

Lead in Food Cans -- Final step in effort to remove lead from food cans; all American manufacturers already comply, but some imported foods still contain lead, which poses a substantial risk to children.

Final Rule Protecting the Identities of Reporters of Adverse Events and Patients -- A final regulation to help ensure that the identities of those who report adverse events associated with human drugs, biologicals, and medical devices and the identities of patients are held in confidence and not disclosed.

Risk assessments and cost benefit analyses are required for major rules, defined as regulations resulting in an annual effect on the economy of \$25,000,000, a major increase in costs or prices, or a significant adverse effect on business, competition, etc. (§ 3201(c)). Peer review is provided for major rules, defined as in § 3201(c), except that the annual effect on the economy must be \$100,000,000 or more (§ 3301(h)). We believe that some of the requirements of H.R. 9 are potentially applicable to most rulemakings that FDA would undertake, including certain product approvals that are done through rulemaking (e.g., annual drug and food additive approvals). Most of the rulemakings scheduled for the next two years likely would be delayed. Assuming no additional resources, and given the cumulative effect this would have on rulemaking, many of these rules could be delayed by more than two years under H.R. 9--thus, delaying the ability of the FDA to address public health concerns and to lessen regulatory burdens in appropriate areas.

6.(B) The procedures required by H.R. 9 are not all new; however, more analyses would have to be performed on many more rulemakings than before. The criteria to be followed in completing a regulatory impact analysis (§7003(c)) are more extensive than those currently followed, and would need to be applied to many more rulemakings than at present. Further, the requirement that the FDA head must certify that the benefits of a final rule justify its costs (Section 3201(a)(5)) would be an entirely new requirement. Similarly, the requirement for risk assessment peer review panels would be new.

6.(C) To the extent that H.R. 9 would create procedural requirements that prior to this legislation were contained only in Executive Orders (which did not create rights enforceable in court), H.R. 9 would permit judicial review of actions previously not reviewable.

6.(D) The following estimates are intended to provide the Committee with an order-of-magnitude type of assessment of the impact of the additional procedural requirements set forth in H.R. 9. The short period of time available for preparation of this information precludes a more analytical response. Again, we are assuming that the question asks the FDA what additional resources would be required to perform the additional steps and issue the regulations in approximately the same timeframes as are currently planned.

The risk assessment, cost/benefit, and peer review requirements of Title III could add as much as several hundred thousand dollars more per regulation over what is currently spent on major regulations. Each peer review panel meeting alone costs approximately \$100,000 for travel, per diem, etc.

The 23-item regulatory impact analysis in Title VII will probably affect every regulation HHS publishes. Assuming that the Department continues to publish several hundred each of proposed and final rules per year, the increased costs associated with requirements of Title VII would likely be in the range of an additional \$150,000 per rule. This assumes that each regulation would require an additional \$100,000 in contract costs for additional analytical work, and additional staff time of 0.5 FTE (\$50,000 including all support costs). Litigation costs could add much more.

6.(E) Given the difficulty in meeting court-ordered or statutory deadlines for such regulations currently, complying with the requirements of H.R. 9 would most certainly make meeting such deadlines problematic.

7. Are the requirements of section 3105 for risk characterization (taking into account the definitions in 3106) consistent with the Department's understanding of sound scientific principles for risk assessment and risk characterization? Would the requirements of section 3105 preclude the Department from considering any information, models, or assumptions in assessing or characterizing risk? How would the Department be able to take into account risks to special subpopulations which may have higher susceptibility than "average"?

As a general matter, the requirements of section 3105 probably could be interpreted so as to be consistent with the FDA's understanding of sound scientific principles for risk

assessment. It should be noted, however, that Section 3105 applies to any characterization of risk, and not just to risk assessment communications. Moreover, many of the specific criteria have little relevance to determinations of non-cancer effects.

The following discussion presents several observations on FDA's uses of risk assessment, and the ways the FDA observes the "principles" set out in section 3105.

Regarding the specifications for ways risk estimates shall be presented, the type of risk estimate apparently "preferred" by Title III is the "best estimate." It is important to recognize that scientists may not always know what the "best" estimate is--hence use of upper-bound estimates. FDA frequently uses upper-bound estimates when making risk-management decisions to protect the public's health.

Consideration of exposure scenarios varies across FDA. The drug and device groups, for example, generally concern themselves with exposures to individual patients when considering products for approval, and furthermore tend to consider plausible, likely (or most efficacious) exposures (or doses). The typical approach when evaluating foods is to consider a wide range of possible exposures, and generally the more probable exposures. This range will most likely include exposure for heavy consumers of the subject food, but not, generally speaking, the most extreme consumer.

Regarding substitution risks, again, FDA does not report such information in any formal way in all the various types of assessments it prepares. In some cases, however, FDA will provide, or require that it be provided such information, such as when a drug company wishes to make comparative efficacy claims against a competitor. In such a case, FDA will require data that compare the applicant's drug's risks (and benefits) to the competitor's drug's risks (and benefits). The substitution risk in this case is that associated with the competitor's drug.

The requirements of H.R. 9, however, taken as a whole, raise a number of very significant policy questions. The inclusion in a statute of a set list of considerations that must be made for every risk-related decision will have numerous adverse consequences. H.R. 9 imposes "one size fits all" requirements on the enormous range of decisions affecting health and safety made by federal regulatory agencies. This can only result in greater inefficiencies and less-effective government. It also deprives FDA management of the ability to make critical decisions regarding allocation of resources to particular problems or categories of problems. It ignores the different statutory mandates under which the executive branch decisions

are being made, and whether those mandates are absolute--as is typically the case with the FD&C Act (prohibition on adulterated or misbranded food, drugs, medical devices in commerce, e.g., food additives prohibited under the Delaney clause, which prohibits any approval of a food additive that is an animal carcinogen).

8. To the extent not already in previous answers, please identify all risk assessment documents, regulatory proposals or decisions, reports to Congress, or other documents made available to the public by the Department which include characterizations of risks that would be subject to the requirements of section 3105.

In FDA, there is a wide range of communications which include characterizations of risk and could be subject, therefore, to the requirements of section 3105. Some of these communications are intended to provide guidance to the industry as to acceptable levels of contaminants, particularly naturally occurring contaminants such as mold. Others are intended to alert medical professionals regarding adverse reactions to approved products or the necessity for careful attention to directions for use where inappropriate use of an approved product has resulted in harm. Some of the more frequently used types of such communications used by FDA are as follows:

- Safety alerts
- Dear Doctor Letters (developed by the company in consultation with FDA)
- Compliance policy guides
- Informal written advice to companies
- Responses to public and congressional correspondence
- Setting of action levels and informing industry of them
- Draft regulations or guidelines
- International Conference on Harmonization (ICH)
- "Points to Consider" publications
- Food additive and color additive regulation preambles
- Product withdrawals

Other parts of the Department engage in a broad and extensive pattern of risk communication. For example, the Office of Health Promotion and Disease Prevention sponsors many activities presenting risk information to consumers. CDC's AIDS information efforts aim at explaining the risk involved in exposures to the HIV virus. NIH sponsors Cancer Line, presenting treatment and risk information to both doctors and patients. Many parts of the Department prepare pamphlets and public service announcements to educate the public about the risks of various diseases. No simple accounting of these and many other efforts exists, but hundreds of millions of dollars are involved. Few of these activities fit the rigid model prescribed under Title III. We can be certain, therefore, that

the strictures of Section 3105 would vastly complicate and perhaps reduce the effectiveness of a host of risk communication activities.

9. Please estimate the cost of complying with the peer review requirements of section 3301, taking into account the provisions of Title VII requiring Regulatory Impact Analyses. How would the Department implement the requirement for peer review of "economic assessments", "economic information," and "cost assessments"? Would the Department be precluded from issuing any regulation until the required peer review, peer review report, and response to the peer review, had been completed and made available to the public? How long would such a process be likely to take? Would such peer review panels be subject to the Federal Advisory Committee Act?

To the extent the FDA has been able to develop cost estimates of the impact of Titles III and VII, they are set forth above.

Title IV gives OMB/CBO one year to issue a report of aggregate costs of all regulations and rules in effect at the time of enactment of H.R. 9. This aggregate cost will necessarily have to be constructed from the costs of each existing regulation because of the contemplated annual management of this budget. Based on previous cost studies by private-sector accounting firms, doing this cost calculation is estimated to cost \$15 million over three years. This level of effort would systematically collect cost experience from several hundred firms in more than 50 discrete industry sectors affected by FDA regulation. Accuracy of estimates in individual sectors, (e.g., OTC drugs, clinical researchers, shellfish shippers, would be exceedingly crude with less than 10 participants in most sectors. Since the bill does not allow three years for cost-efficient collection of this information, compression into one year would probably cost \$25 million because of the concurrent data collection in all industry sectors.

The bill appears to preclude the Department from issuing a regulation until all of the peer review requirements are completed and made public. In addition, the bill would require that the President establish a National Peer Review Panel to evaluate the peer reviews of each agency and report to Congress.



DEPARTMENT OF AGRICULTURE  
OFFICE OF THE SECRETARY  
WASHINGTON, D.C. 20250

01 SEP 1995

Honorable George E. Brown, Jr.  
Ranking Democratic Member  
Committee on Science  
2320 Rayburn House Office Building  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Brown:

Thank you for the opportunity to respond to Title III and other provisions of H.R. 9, the Job Creation and Wage Enhancement Act of 1995.

Title III, Title VII, and other provisions of the Act would have a significant impact on the regulatory development process in the Department of Agriculture (USDA). The diversity in purpose and outreach of USDA's programs concerning human health, safety, and the environment contribute to the large body of regulation published annually by USDA. Regulatory activities that are required by law, are necessary to interpret the law, or are made necessary by compelling public need would be extremely difficult, if not impossible, to accomplish in accordance with the requirements of the Act.

Moreover, Section 304 of P.L. 103-354 establishes the Office of Risk Assessment and Cost Benefit Analysis (ORACBA) in USDA. ORACBA is responsible for ensuring that the analysis conducted by USDA of major regulations which have the primary purpose of regulating issues of human health, human safety, or the environment are performed consistently and include a risk assessment and cost-benefit analysis that is based on reasonably obtainable and sound scientific, technical, economic and other data. These requirements apply to rules issued beginning in April 1995. The implementation of P.L. 103-354 will address many of the concerns which underlie the proposed legislation.

USDA objects to provisions relating to risk assessment and cost benefit analysis. The types of hazards addressed by USDA programs are exceedingly diverse and do not conform to the requirements for risk assessment identified in the legislation. H.R. 9 would limit the types of risk assessment methods appropriate to adequately evaluate hazards addressed by USDA programs in the areas of food safety, human nutrition, plant and animal health and inspection, and the environment.

The scope of coverage concerning risk assessments, the analysis of certain factors, peer review requirements, and other requirements would significantly increase the time between the appearance of a hazard, especially those relating to human health, and the taking of appropriate measures. Regulatory responses to human health risk must often anticipate the

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Honorable George E. Brown, Jr.

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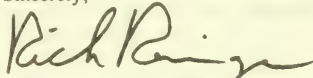
introduction of the particular hazard such as a foodborne pathogen. The inability to respond in a timely manner to such risks would result in significant costs to human health and economic losses.

The provisions of the Act could also be interpreted in a manner that would hinder economic opportunities and obstruct trade. Barriers to investigation and enforcement of regulatory programs that ensure disease free quality of exported agricultural products would threaten multi-million dollar export industries. Efforts to investigate violations of import regulations would be similarly restricted. Risk assessment procedures mandated in H.R. 9 could be interpreted to deviate considerably from established international standards supported in the General Agreement on Tariffs and Trade and the North American Free Trade Agreement. These procedures require consistent and timely measures when establishing sanitary and phytosanitary measures to achieve the appropriate level of protection.

The Office of Management and Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

The responses to your questions are enclosed.

Sincerely,

A handwritten signature in dark ink, appearing to read "Rich Rominger", is written over the typed name.

RICHARD E. ROMINGER  
Acting Secretary

Enclosures

## QUESTIONS SUBMITTED BY CONGRESSMAN BROWN

1. Please identify the programs in the Board which would be subject to the requirements of the Risk Assessment and Communication Act of 1995 (Title III of H.R. 9), taking into account Title VII and other relevant sections of H.R. 9.

**Response:** The National Transportation Safety Board has no substantive regulatory authority. The Safety Board has been tasked by the Congress to investigate and determine the facts, conditions, circumstances and the probable cause(s) of transportation accidents. The Congress further called upon the Safety Board to propose corrective steps to make the transportation of persons as safe and free from risk of injury as is possible, and to recommend and advocate meaningful responses to reduce the likelihood of recurrence of transportation accidents similar to those investigated by the Safety Board. (Public Law 93-633 "Independent Safety Board Act of 1974" -- Section 304 "Duties of the Board")

2. Using the definitions of "risk assessment" and "risk characterizations" set out in section 3107 of the Act, how many risk assessments and risk characterizations were prepared by, or on behalf of, the programs in the Board over the last fiscal year? Of those, how many would be considered to be a "screening analysis" exempted under Section 3103(b)(2)?

**Response:** The Safety Board did not develop any formal risk assessments or risk characterizations in FY 1994, although analysis that identifies and characterizes hazards and that attempt to quantify the degree of vulnerability of individuals and populations to those hazards is contained in the Board's accident reports and safety studies. These analyses would all be considered screening analyses as described in Section 3103(b)(2).

3. Please describe the Board's present practices, including references to any published guidelines or procedures, relating to risk assessment, risk characterization, cost-benefit analysis, or peer review.

**Response:** The Safety Board does not have any formal practices, guidelines or procedures relating to risk assessment, risk characterization, cost benefit, or peer review.

4. If enacted into law, how would the Act affect the Board's present practices as described in question 3? If compliance with the Act would require additional resources in carrying out such practices, please estimate the additional resources (in terms of dollars and personnel) that would be required to carry out the provisions of the Act.

**Response:** H.R. 9 would have little or no effect on the Safety Board's present practices, and no additional resources would be required by the Safety Board. Indirect effects on the Safety Board's recommendation process are, however, both likely and difficult to estimate. Virtually all of the Board's recommendations to Department of Transportation (DOT) modal agencies (as well as to other agencies and organizations) would require the exercise of a formal and potentially time-consuming and costly risk assessment process. It is likely that the net effect would be to reduce and delay the response to Safety Board recommendations.

**Question 1. Identify the programs in the Department which would be subject to the requirements of the Risk Assessment and Communication Act of 1995, taking into account Title VII and other relevant sections of H.R. 9.**

**ANSWER:**

Because of the scope of the regulation and the definition of a major rule, a large number of USDA programs would be subject to the requirements of the Act. The agencies of the Department that administer programs protecting human health, safety or the environment include: Agricultural Marketing Service, Animal and Plant Health Inspection Service, Consolidated Farm Service Agency, Food and Consumer Service, Forest Service, Natural Resource Conservation Service, and the Food Safety and Inspection Service. The major programs that would be subject to the requirements of the Title III include: the Conservation Reserve Program, the Wetland Reserve Program, the Food Stamp Program, Supplemental Program for Women, Infants, and Children, Child Nutrition Programs, programs established by the Federal Meat and Poultry Products Acts, and programs administered by the Forest Service. Title VII would affect nearly every USDA program.

**QUESTION 2: Using the definition of "risk assessment" and "risk characterization" set out in section 3107 of the Act, how many risk assessments and risk characterizations were prepared by, or on behalf of the programs in the Department over the last fiscal year? Of those, how many would be considered to be a screening analysis exempted under 3103 (b)(2)?**

**ANSWER:**

Prior to the passage of H.R. 4217, the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, the Department of Agriculture was required to prepare risk assessments in limited situations. For example, the Department prepares risk assessments in connection with the cleanup of hazardous waste sites under environmental law. Risk analysis is also being used by a number of agencies in program management decisions and regulatory development.

It is difficult to give a precise estimate of the number risk assessments and risk characterizations prepared in the Department over the last fiscal year. Title III, Sec. 3105, of H.R. 9 which indicates that Federal agencies would be subject to the conditions of the Act when characterizing risk in any risk assessment document, regulatory proposal or decision, report to Congress, or other document which is made available to the public could be interpreted to include every public notice, permit, statement, or decision issued by USDA agencies on a routine basis to protect human health, safety, or environmental resources. If so, the complexity of risk characterizations which these documents would increase considerably. See the response to Question 8 for more information on this issue.

During the last fiscal year, the Department of Agriculture published 206 significant or economically significant rules and about 400 rules that were not significant. Additionally, there are a number of rules that are currently exempt from formal regulatory impact analysis

because the regulations produce results that are determined by formulae contained in legislation or that are time sensitive.

Pursuant to Sec. 3201 of H.R. 9, which includes the requirement to prepare risk assessments and cost-benefit analyses, and the definition of a major rule, it is estimated that at least 200 of the regulations promulgated in FY 1994 would have required a risk assessment under the requirements of H.R. 9. This estimate excludes regulations considered to be a screening assessment.

**QUESTION 3: Please describe the Department's present practices, including references to any published guidelines or procedures, relating to risk assessment, risk characterization, cost benefit analysis, or peer review.**

**ANSWER:**

Risk Assessment and Risk Characterization The Office of Risk Assessment and Cost Benefit Analysis (ORACBA) was established in the Department by Section 304 of P.L. 103-354, the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994. ORACBA is responsible for ensuring that the analysis conducted by the USDA of major regulations which have the primary purpose of regulating issues of human health, human safety, or the environment are performed consistently and include a risk assessment and cost-benefit analysis that is based on reasonably obtainable and sound scientific, technical, economic and other data. These requirements apply to rules issued beginning in April 1995. Specific guidance for ORACBA is currently under review. The draft guidance adheres to the enabling legislation and draft OMB principles for risk assessment, management and communication.

The objective of risk assessment and cost-benefit analysis under this guidance is to provide a clear understanding of the relative risks introduced by various hazards to human health, safety and the environment and the cost to the government for regulating those risks. In achieving this objective, policy officials are better able to set priorities, determine whether the regulation will protect against the risk and produce benefits in a cost-effective manner; and the general public and regulated group is better able to understand the reasons for these regulations.

For USDA purposes, a risk assessment is a review and evaluation of hazards to human health, human safety, and the environment, using reasonably obtainable and sound scientific, technical, economic and other information to accurately characterize the nature and magnitude of these hazards and to clearly communicate what is known and not known about these hazards to policy officials and the general public. A risk assessment should include an estimate of the uncertainty associated with occurrence of the hazard.

P.L. 103-354 contains the following requirements:

#### A. Statutory Requirements

The analysis prepared by the Department of a relevant proposed major regulation as defined will evaluate the following with as much specificity as possible:

1. The risk to human health, human safety, or the environment, and any combination thereof, addressed by the regulation, and where applicable and practical, the health and safety risks to persons disproportionately exposed or particularly sensitive;
2. The cost associated with the implementation of and compliance with the regulation;
3. Where appropriate and meaningful, a comparison of the risk to other similar risks regulated by the Department or other Federal Agencies resulting from comparable activities and exposure pathways (such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks and the preventability or nonpreventability of risks); and
4. The quantitative and qualitative benefits of the regulation, including the reduction or prevention of the risks expected from the regulation.

When the analysis is not practical because of compelling circumstances, the Director is required to provide an explanation as a substitute for the analysis. The analysis will be published in the Federal Register.

The Secretary of Agriculture is required to state in the regulatory analysis whether the regulation:

1. Advances the purpose of protecting against the identified risk, and
2. Produces benefits and reduces risks to human health, human safety, or the environment and any combination thereof in a cost effective manner as a result of the implementation of and compliance with the regulation, by local, State, and Federal Government, and other public and private entities as estimated.

#### B. Operating Procedures.

Department guidance concerning the operations of ORACBA is currently under review. Draft guidance is as follows.

Beginning in April 1995, ORACBA will coordinate and review all risk assessments and cost-benefit analyses prepared in the Department in support of major regulations whose primary purpose is to regulate human health, human safety, or the environment. The objective of review and coordination is to assure that such assessments and analyses are methodologically sound, objective, consistent and use the best available scientific, technical, economic information and data. ORACBA also will undertake other activities to support this mission. Specific functions of ORACBA are to:

1. Maintain a reservoir of expertise in risk assessment and cost benefit analysis. The office will facilitate across USDA agencies and with the general public the sharing of risk information, including access to and transfer of biological, economic, geographic, and other information related to USDA risk assessments;
2. Establish a panel of qualified individuals to review agency risk assessment methodologies, major USDA risk assessments and, when requested by the Director of ORACBA, ascertain whether they meet established standards;
3. Develop for public comment and Agency approval, regulations which state methods used by USDA agencies for conducting risk assessments;
4. Develop guidelines for the review of an existing risk assessments when warranted by the development of new and significant scientific information;
5. Provide direction to Department agencies in the appropriate methods of risk assessment and cost benefit analysis;
6. Coordinate, review and approve risk assessments and cost benefit analyses prepared in support of major regulations affecting human health, human safety, and the environment;
7. Participate in planning and developing research and training programs related to improving the Department's capability to perform risk assessments and cost benefit analyses;
8. Represent the Department and provide a focal point within the Department on matters related to risk assessment and cost benefit analyses;
9. Provide assistance to the Office of the Chief Economist in the areas of risk assessment, cost benefit analysis, policy analysis, policy evaluation and legislative analysis; and
10. Develop programs to encourage the use of risk assessment in reviewing agency priorities and critical decisions.

### C. Guidelines for Risk Analysis

The guidelines for risk analysis emphasize that risk analysis is a tool for analyzing and establishing risk priorities, that risk analysis is an ongoing process, and that USDA guidelines should be sufficiently flexible to incorporate scientific advances. USDA will employ the best, reasonably obtainable information from the natural, physical, and social sciences to assess risks to human health, safety and the environment. Risk characterizations should be both qualitative and quantitative and judgements in risk assessment should be stated explicitly. Risk assessments should encompass all appropriate hazards. Principles for risk management and risk communication will be developed in accordance with appropriate standards and guidance.

D. Cost-Benefit Analysis and Peer Review. The Department guidance for cost-benefit analysis and other regulatory procedures is being revised to reflect the activities of ORACBA. This document is being revised to reflect the activities of ORACBA. The instructions for preparing cost-benefit analysis pertain to significant, economically significant, and major rulemakings. The instructions require: (1) an overview of program issues, need for rulemaking, and options considered; (2) the statutory authority; (3) an assessment of economic costs, benefits and other significant effects; (4) reasons for the selection of the proposed alternative; and (5) public comments received and response to comments.

Risk assessments are conducted using other Federal agency guidelines such as EPA's, or in cooperation with States in connection with the cleanup of hazardous waste sites.

**QUESTION 4: If enacted into law, how would the Act affect the Department's present practices as described in question 3? If compliance with the Act would require additional resources in carrying out such practices, please estimate the additional resources (in terms of dollars and personnel) that would be required to carry out the provisions of the Act.**

**ANSWER:**

The programs of the Department are diverse and far-reaching, as are the regulations that attend their delivery. Regulations codify how the Department will conduct its business including the specifics of access to and eligibility for USDA programs. Regulations also specify the behavior of State and local governments, private industry, businesses, and individuals necessary to comply with their provisions. The regulations of the Department range from nutrition standards for the school lunch program, to natural resource and environmental measures governing National Forest usage and soil conservation, to regulations protecting American agribusiness from the ravages of domestic or foreign plant or animal pestilence, and extend from farm to supermarket to ensure the safety, quality, and availability of the Nation's food supply. Many regulations function in a dynamic environment which requires their periodic and sometimes immediate modification. The factors determining various entitlement, eligibility, and administrative criteria often change

from year to year. Therefore, many significant regulations must be revised annually to reflect changes in economic and market benchmarks. Almost all legislation that affects USDA programs has accompanying regulatory needs, often with a significant impact.

Regulatory responses to human health risks must often anticipate the introduction of the particular hazard such as a foodborne pathogen or the introduction of a plant or animal pest. H.R. 9 could be interpreted to cause delays in the investigatory, sampling and testing programs, and appropriate actions to halt food contaminants such as E. coli O157:H7, a potentially deadly bacterium, and other contaminants of meat or poultry products. In some cases, actions need to be implemented immediately. The scope of coverage concerning risk assessments as well as the analysis of certain factors would potentially increase the time between determination of the presence of an contaminant and the taking of appropriate measures. Other provisions would potentially impede a timely, effective, and cost-efficient investigation of the cause and source of contamination in meat and poultry products.

Other efforts to prevent hazards from becoming emergencies through (1) control of gypsy moth, the fire ant, the boll weevil, grasshoppers and other destructive insects and pests; (2) prevention of exotic plants and animals from entering the United States; and (3) control of animal agents that can affect human health. These efforts also prevent significant economic losses in the food and livestock industry.

Provisions of the Act could hinder economic opportunities and obstruct trade. For example, barriers to investigation and enforcement of regulatory programs that ensure the disease free quality of exported agricultural products could threaten multi-million dollar export industries. Efforts to investigate violations of import regulations would be similarly restricted. Furthermore, regulatory efforts to protect resources on Federal lands could be restricted by the elaborate H.R. 9 risk assessment process.

Risk assessment procedures mandated in H.R. 9 could be interpreted to restrict world trade. Procedures in GATT and NAFTA require consistent and timely procedures when establishing sanitary and phytosanitary measures to achieve the appropriate level of protection. Deviations from established international standards must be defended or trade sanctions could be imposed.

H.R. 9 could be interpreted to limit the types of risk assessment methods and to require the use of methods that would be inappropriate for hazards often addressed by USDA. USDA programs in the areas of food safety, human nutrition, plant and animal health and inspection, and the environment often address hazards which cannot be adequately assessed solely with the use of quantitative methods as required by H.R. 9.

Compliance with the Act would require additional resources to carry out such activities. An estimate of cost is provided in the response to Question 6.

**QUESTION 5:** How does the Department obtain the information it uses to prepare risk assessments, cost-benefit analyses, or risk characterizations? Does the Department rely in part upon the private sector in providing the information needed by the Department to conduct such assessments or analyses? If so, would the Act require the Department to obtain additional information from the private sector in order to comply with the Act's requirements.

**ANSWER:**

The question requires a projection of conditions under which the Department would be conducting risk assessments with which it has very limited experience at this point. Many agencies of the Department do not have the personnel or resources to respond fully to the requirements of Title III.

Much of the information currently used in conducting risk assessments in the Department is developed internally. However, the type of information required to satisfy conditions for risk assessment in Title III either does not currently exist for the type of hazards often addressed in USDA or can not be developed because of ethical reasons. USDA can not conduct experimental or epidemiological studies on foodborne pathogens. Humans are usually the only effected organisms. Many animal species are not affected by the pathogens. Therefore, human illness data are used. Either the scientific research agencies of the Department would be required to significantly reorient their missions or such studies necessary to provide the information would be contracted from the private sector, if funds were available.

**QUESTION 6:** Please identify the regulations expected to be proposed or promulgated in the next two years which would require a Regulatory Impact Analysis under Title VII, an analysis of risk reduction benefits and costs or a certification under Subtitle B of Section 3201, or peer review under Section 3301 . What additional procedures would the Department be required to follow to issue such regulations if the Act were enacted into law? Would the Act permit judicial review of agency actions beyond what is presently permitted under the Administrative Procedure Act? Please estimate the additional time and resources that would be necessary to complete the expected rulemaking following the required procedures. If the Department is subject to court-ordered or statutory deadlines for completion of any such regulations, can the Department comply with the Act and still meet such deadlines?

**ANSWER:**

The Regulatory Plan of the USDA was published in the Federal Register, Vol. 59, No. 218, November 14, 1994, pp. 57010-57029. The Regulatory Plan identifies the major regulatory priorities of the USDA for the next 12 months. In that same Volume of the Federal Register, pp. 57250-57370, the Department also issued its semiannual regulatory

agenda, which identifies specific rulemaking activities anticipated for the coming 12 months. The Regulatory Agenda identifies all anticipated rulemaking activities of the Department.

It is not possible to estimate the regulatory development activities of the Department beyond the coming year. The 1995 Farm Bill will require a substantial number of regulations that will be subject to the requirements of Title III and Title VII.

Concerning the issue of whether the Act would permit judicial review of agency actions beyond that permitted under the Administrative Procedures Act, Section 6001 of H.R. 9 would repeal 5 U.S.C. 611 which specifically exempts from judicial review, with certain exemptions, determinations by agencies concerning the applicability of the Regulatory Flexibility Act to any action of the agency. Thus, enactment of H.R. 9 would permit review of actions not currently reviewable.

If the Department is subject to court ordered or statutory deadlines, every effort is made to meet those deadlines.

The Department currently conducts 10-12 regulatory impact analyses annually of economically significant rules which among other criteria are defined to have an annual economic impact of at least \$100 million. The cost of each of these analyses ranges from \$200,000 to \$400,000 depending on their complexity. The definition of a major rule in Title VII would increase the number of rules requiring a regulatory impact analyses to about 400, many would not require extensive or complex measures. The cost of conducting regulatory impact analyses in the Department would increase accordingly. The cost for conducting such regulatory impact analyses is conservatively estimated at \$15 million.

The Department estimates that about 200 risk assessments concerning human health, safety or the environment would be required over the coming year if section 3201 were enacted. The cost of an individual risk assessment is estimated at \$150,000 to \$500,000 depending on the complexity of the analysis. Assuming that the cost of the risk assessment would decline for less complex or comprehensive risk assessment, the cost of implementing these provisions would be about \$25 million. This amount could escalate considerably if the requirements were strictly interpreted to require only quantitative assessments.

Each risk assessment for programs concerning human health, safety, or the environment would require a peer review if the annual economic effect were at least \$100 million, or other conditions stated in Title III applied. The Department anticipates that at least 5 such regulations would be prepared in the next year. The costs of peer review for such regulations are conservatively estimated to range from \$100,000 to \$250,000. The costs of peer reviews for these regulations are estimated at \$1 million.

**QUESTION 7:** Are the requirements of section 3105 for risk characterization (taking into account the definitions in 3106) consistent with the Department's understanding of sound scientific principles for risk assessment and risk characterizations? Would the

**requirements of section 3105 preclude the Department from considering any information, models, or assumptions in assessing or characterizing risk? How would the Department be able to take into account risks to special subpopulations which may have higher susceptibility than "average"?**

**ANSWER:**

The requirements of section 3105 are not consistent with the Department's understanding of sound scientific principles for risk assessment and characterizations for the types of hazards often addressed by USDA programs. The requirements could be interpreted to apply to types of hazards that can be evaluated using laboratory or population studies. Ethical considerations prevent such procedures in evaluating measures to control food borne pathogens. Qualitative information and expert opinion and a broader range of methodologies are required in such analyses. See the response to Question 4 for further information.

**QUESTION 8. To the extent not already addressed in previous answers, please identify all risk assessment documents, regulatory proposals or decision, reports to Congress, or other documents made available to the public by the Department which include characterizations of risks that would be subject to the requirements of section 3105.**

**ANSWER:**

The Department issues documents and notices to the public, numbered in the thousands, which could be interpreted as being subject to the requirements of section 3105. For example, the Forest Service issues, on a very frequent and often daily basis at each of the National Forests, notices concerning fire hazards and actions which are taken in response to fire conditions that affect the public use. Similarly, the Veterinary Service issues a very large number of decisions or notices concerning types of hazards addressed under their programs.

**QUESTION 9. Please estimate the cost of complying with the peer review requirements of section 3301, taking into account the provisions of Title VII requiring Regulatory Impact Analyses. How would the Department implement the requirement for peer review of "economic assessment", "economic information" and "cost assessments"? Would the Department be precluded from issuing any regulation until required peer review, peer review report, and response to the peer review, had been completed and made available to the public? How long would such a process be likely to take? Would such peer review panels be subject to the Federal Advisory Committee Act?**

**ANSWER:**

Once a risk assessment is completed, arrangements for establishing a peer review may take an equal amount of time. The actual peer review may take an additional (but equal) amount of time. The result is a significant expansion in the regulatory development period. In addition, requirements for "Regulatory Impact Analysis" will further increase time required and resources for final decisions. This adds additional levels of review prior to implementation, which is inconsistent with the intent of National Performance Review. To require public evaluation of the risk assessments and peer review, as required in the Act, would add tremendous pressures to the process of regulatory development.

The Federal Advisory Committee Act would apply to the peer review panels unless they are comprised totally of full-time Federal employees.

**National Transportation Safety Board**

Washington, D.C. 20594

Office of the Chairman

February 1, 1995

Honorable George E. Brown, Jr.  
Ranking Democratic Member  
Committee on Science  
House of Representatives  
Washington, D.C. 20515

Dear Congressman Brown:

This is in response to your January 20, 1995, letter regarding the impact on the Safety Board of Title III (Risk Assessment and Cost/Benefit Analysis for New Regulations) of H.R. 9, the Job Creation and Wage Enhancement Act of 1995. Enclosed are the Safety Board's responses to the questions submitted, along with a copy of the Independent Safety Board Act Amendments.

The Safety Board has no substantive regulatory authority and, consequently, the provisions of H.R. 9 would not directly affect our operations. Many of the safety recommendations we issue do require agencies to initiate rulemaking to improve transportation safety, so H.R. 9 could indirectly affect the acceptance rate of the recommendations issued as a result of our investigations.

The Safety Board has noted in a number of recent accident reports that there is a problem with the timeliness of much needed transportation safety regulations. It has been the Board's experience that even current procedures for issuing regulations in the area of transportation safety take an undue amount of time. We are concerned that the requirements proposed in H.R. 9 could create further, unnecessary delays in the implementation of transportation safety regulations. We encourage you to consider this aspect in your deliberations on this legislation.

If you have questions, or if we can be of additional assistance, please do not hesitate to contact us.

Sincerely,

A handwritten signature in dark ink, appearing to read "Jim Hall".

Jim Hall  
Chairman

Enclosure

cc: Honorable Robert S. Walker  
Chairman, Committee on Science

5. How does the Board obtain the information it uses to prepare risk assessments, cost-benefit analyses, or risk characterizations? Does the Board rely in part upon the private sector in providing the information needed by the Board to conduct such assessments or analyses? If so, would the Act require the Board to obtain additional information from the private sector in order to comply with the Act's requirements?

**Response:** The screening analyses of risk contained in Safety Board accident reports and safety studies utilize data and information from Board investigations, DOT modal agencies, and the private sector. The legislation would not require the Board to obtain additional information from the private sector.

6. Please identify the regulations expected to be proposed or promulgated in the next two years which would require a Regulatory Impact Analysis under Title VII, an analysis of risk reduction benefits and costs or a certification under Subtitle B of Section 3201, or a peer review under Section 3301. What additional procedures would the Board be required to follow to issue such regulations if the Act were enacted into law? Would the Act permit judicial review of agency actions beyond what is presently permitted under the Administrative Procedure Act? Please estimate the additional time and resources that would be necessary to complete the expected rulemaking following the required procedures. If the Board is subject to court-ordered or statutory deadlines for completion of any such regulations, can the Board comply with the Act and still meet such deadlines?

**Response:** The Safety Board does not expect to propose or promulgate any regulations in the next two years which would require a regulatory impact analysis under H.R. 9.

7. Are the requirements of section 3105 for risk characterization (taking into account the definitions in 3106) consistent with the Board's understanding of sound scientific principles for risk assessment and risk characterization? Would the requirements of section 3105 preclude the Board from considering any information, models, or assumptions in assessing or characterizing risk? How would the Board be able to take into account risks to special subpopulations which may have higher susceptibility than "average"?

**Response:** Because the Safety Board's assessments and characterization of risk are restricted to screening analysis, the requirements of Section 3105 would not affect Board accident reports or safety studies. The Board is not in a position to comment on the scientific basis of the formal risk assessments and risk characterizations.

8. To the extent not already addressed in previous answers, please identify all risk assessment documents, regulatory proposals or decisions, reports to Congress, or other documents made available to the public by the Board which include characterizations of risks that would be subject to the requirements of section 3105.

**Response:** The Safety Board has no documents as described in question 8.

9. Please estimate the cost of complying with the peer review requirements of section 3301, taking into account the provisions of Title VII requiring Regulatory Impact Analyses. How would the Board implement the requirement for peer review of "economic assessments," "economic information," and "cost assessments"? Would the Board be precluded from issuing any regulation until the required peer review, peer review report, and response to the

peer review, had been completed and made available to the public? How long would such a process be likely to take? Would such peer review panels be subject to the Federal Advisory Committee Act?

**Response:** Question 9 is not applicable to the Safety Board.



THE SECRETARY OF THE TREASURY  
WASHINGTON

February 1, 1995

The Honorable George E. Brown, Jr.  
Ranking Member  
Committee on Science  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Brown:

Thank you for your letter of January 20, 1995, requesting the views of the Department of the Treasury on title III of H.R. 9, and related provisions of title VII of the bill.

The primary missions of the Department of the Treasury are: protecting and collecting the revenue under the Internal Revenue Code and Customs laws; supervising national banks and thrift institutions; managing the fiscal operations of the Federal government; enforcing laws relating to counterfeiting, Federal government securities, firearms and explosives, foreign commerce in goods and financial instruments, and smuggling and trafficking in contraband; protecting the President, Vice President, and certain foreign diplomatic personnel; training Federal, State and local law enforcement officers; and producing coins and currency. Consistent with these missions, most programs and regulations of the Department and its constituent bureaus are promulgated to interpret and implement the laws as enacted by the Congress and signed by the President.

The Department of the Treasury currently does not utilize risk assessments in conjunction with its programs and regulations, which are significantly different from programs and regulations that concern the environment, workplace safety or standards for food and drugs. Title III of H.R. 9, however, could be interpreted to apply to a wide range of Treasury programs and regulations. This is because title III does not define what constitutes a program or regulation "designed to protect human health, safety, or the environment." As a result, title III could require this Department to expend scarce resources on risk assessments for programs and regulations that we do not believe should be within the scope of title III.

For example, the U.S. Customs Service is responsible for enforcing laws prohibiting the importation of narcotics and other controlled substances into the United States, as well as the regulations of numerous other Federal agencies that prohibit the importation of certain merchandise (e.g., unsafe meat and food products). Because these regulations do protect human health and safety, title III as currently drafted could require detailed

risk assessments for all Customs regulations regarding the entry or inspection of imported merchandise. We seriously question whether this is appropriate.

The Bureau of Alcohol, Tobacco and Firearms (BATF) issues regulations to implement provisions of criminal statutes concerning firearms, such as the waiting period specified in the Brady law, and the ban on certain assault weapons and large capacity magazines. BATF also occasionally issues regulations that prohibit or permit the use of certain materials in the manufacture of wine, malt beverages or distilled spirits. Because these regulations protect human health and safety, title III could require the preparation of risk assessments. Again, we question whether this is appropriate.

The Internal Revenue Service (IRS) issues regulations that interpret and implement provisions of the Internal Revenue Code of 1986. Many of these regulations implement provisions of the tax code that are designed to encourage activities that protect human health or the environment. Examples include IRS regulations concerning the alcohol fuel tax credit, the vaccine excise tax (which supports a trust fund for persons injured by vaccines), the tax credit for electricity produced from renewable resources, tax exempt bonds (including those issued by municipalities for sewerage and waste treatment facilities, and by hospitals), the tax credit for electric vehicles, and the deduction for clean fuel vehicles. As currently drafted, title III would probably require the IRS to prepare detailed risk assessments in connection with these and similar regulations. Again, we do not believe that such regulations should be within the scope of title III.

The Financial Management Service (FMS) is the Government's banker, responsible for hundreds of millions of checks and electronic payments annually. Payments are made to individuals for Social Security, to health care providers under Medicare and Medicaid, and to States, municipalities and local governments for a wide variety of Federal assistance and grant programs that affect human health, safety, or the environment. As drafted, title III could require risk assessments for all FMS regulations governing payments for these and similar activities.

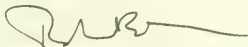
For these reasons, we strongly urge that title III be clarified to define agency regulatory programs for which risk assessments are intended.

Finally, the relationship between the peer review requirements in title III and regulatory impact analyses prepared pursuant to title VII is unclear. Section 3301(a) directs agencies to develop a systematic program for peer review of regulatory programs addressing human health, safety and the environment. Section 3301(b), however, requires that agencies provide for peer

review of any cost assessment prepared in connection with a major rule, and authorizes the Director of the Office of Management and Budget to order a peer review for certain other cost assessments. Section 3301(c)(3) also contains a reference to economic assessments. Because neither title III nor title VII contains a cross reference to the other, it is unclear whether the references in section 3301 to cost assessments and economic assessments are intended to refer to materials prepared in connection with major regulations affecting human health, safety, or the environment, or to regulatory impact analyses prepared for other major rules pursuant to title VII. We believe that title III should be clarified to provide that peer review does not apply to regulatory impact analyses prepared under title VII.

Please find enclosed answers to the specific questions that accompanied your letter. If you or your staff have any questions or require additional information, please contact Richard S. Carro, Associate General Counsel (622-1146).

Sincerely,



Robert E. Rubin

Enclosure

## DEPARTMENT OF THE TREASURY

Answers to Questions Concerning  
Titles III and VII of H.R. 9

1. The scope of title III is unclear. Without further clarification it could reach a wide range of Treasury programs and regulations. For example, Treasury regulations such as those described in the letter transmitting these answers could be subject to risk assessments if they fall within the definition of "major rule" in section 3201(c)(2).
2. None.
3. The Department has no present practices relating to risk assessment, risk characterization or peer review. As explained in the letter transmitting these answers, we do not believe Treasury programs and regulations concerning human health, safety, or the environment are the types of programs or regulations intended to be covered by title III. With respect to cost-benefit analyses, if applicable to a Treasury regulation, the Department adheres to guidance provided by the Office of Management and Budget in connection with Executive Order 12866. The Office of the Assistant Secretary (Economic Policy) has expertise to provide assistance in the preparation of cost-benefit analyses and economic elements of risk assessments.
4. To the extent that regulations issued by any Treasury office or bureau are deemed major regulations designed to protect human health, safety, or the environment, the Department will be required to engage in risk assessments that it does not currently prepare, and to establish a peer review program.

Section 3301(a) requires a peer review program to be applicable "across the agency." The term "agency" is not defined in subtitle C. The only definition of this term in title III is in subtitle A; if this definition applies the Department would be required to establish a department-wide peer review program notwithstanding the fact that the underlying regulatory action occurs at the bureau level with departmental review. We believe it may be more appropriate to permit peer review programs to be established at the bureau level because of their regulatory expertise. Moreover, establishing peer review programs at this level will ensure that bureaus that do not have programs or regulations designed to protect human health, safety, or the environment do not expend resources to establish such programs.

Although we cannot predict whether any future Treasury regulation affecting human health, safety, or the environment will be a section 3201(c) major rule subject to risk assessment or a section 3301(h) major rule subject to peer review, title III nevertheless would appear to require the Department to develop a "systematic program" for peer review. While the establishment of such a program will require additional personnel and budgetary resources, we are not now able to provide an estimate of these resources.

5. When the Department prepared regulatory impact analyses under E.O. 12291 in connection with a few regulations affecting financial institutions, the Department did in part rely on information provided by the private sector. To the extent that the Department may be required to prepare risk assessments under title III, substantial additional information would be required from the private sector to comply with this requirement.
6. During calendar year 1994, the Department issued approximately 300 regulations (over 40 percent of which were tax regulations issued by the IRS). This level of regulatory activity is comparable with recent years and is likely to continue during the next two years.

Regulatory Impact Analyses: Title VII of H.R. 9 requires the preparation of a regulatory impact analysis for every major rule. Section 7004(b) defines a major rule as any rule that (1) affects more than 100 persons or (2) compliance with which will require the expenditure of more than \$1 million by any person<sup>1</sup>.

We believe the definition of major rule is over-inclusive. Because virtually each regulation issued by the Department affects more than 100 persons, we estimate that at least 250 of these regulations would be "major" rules under title VII requiring the preparation of a regulatory impact analysis<sup>2</sup>.

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<sup>1</sup> Section 7004(b)(2) does not define the time period within which such compliance costs must be incurred. Accordingly, it appears that a rule would be a major rule under this paragraph even if such costs were incurred over many years or decades.

<sup>2</sup> This estimate assumes that the reference to E.O. 12291 in section 7004(a) exempts from the requirements of title VIII (1) rules concerning a foreign or military affairs function of the United States and (2) rules relating to agency organization, management or personnel.

Moreover, because the E.O. 12291 definition of "rule" or "regulation" is so broad, it could encompass a number of activities that traditionally have not been considered regulatory (e.g., Customs tariff reclassifications, IRS revenue rulings and revenue procedures, similar rulings documents issued by other Treasury bureaus, as well as some internal legal opinions). If such actions are within the scope of title VII, the number of Treasury actions annually subject to regulatory impact analyses would easily double.

Risk Assessments and Peer Reviews: Given the uncertainty of the scope of title III (see the letter transmitting these answers), we cannot estimate which or how many Treasury regulations may be subject to risk assessments or peer reviews in the next two years.

Additional Procedures: Titles III and VII would impose substantial additional procedures for Treasury regulations. A title VII regulatory impact analysis consists of 23 elements; each regulation and accompanying analysis also would have to be transmitted to the Office of Management and Budget for review and a "good writing" certification under sections 7005 and 7006. To the extent that Treasury regulations are considered to be designed to protect human health, safety, or the environment, the additional procedures of section 3201(a) would apply to such regulations that are section 3201(c)(2) major rules, as would the additional procedures of section 3301 if such regulations are section 3301(h) major rules.

The requirements of titles III and VII are likely to impede the rulemaking process, particularly if regulatory impact analyses are subject to judicial review. Although it is likely that these requirements may make it difficult for agencies to comply with statutory or judicial deadlines (or impossible in the case of short deadlines or highly complex regulations), we cannot predict whether this will be a particular problem for the Department.

Judicial Review: With respect to title III, section 3301(e) provides that peer reviews are within the scope of review when a final agency action is otherwise subject to judicial review. This suggests that risk assessments that are subject to peer review also would be before the court. It is not clear, however, whether a risk assessment prepared for a rule that was not subject to peer review would be before the court.

The extent to which agency compliance with title VII is subject to judicial review is unclear. We note that a 1994 draft of H.R. 9 contained a provision permitting citizen suits; that provision is not in title VII as introduced.

This fact, together with the explicit authorization of judicial review of title III peer reviews in section 3301(e) and the absence of a similar provision in title VII, strongly suggests that any judicial review of regulatory impact analyses is not intended. Such an approach would be consistent with the terms of both E.O. 12291 and E.O. 12866.

A contrary interpretation, however, may be inferred from an analysis of section 6001(a) of H.R. 9. That section would repeal section 611 of the Regulatory Flexibility Act (5 U.S.C. 611), which provides for judicial review of analyses prepared under that Act in a manner similar to the judicial review provided for in section 3301(e). Since the intent of section 6001(a) appears to be to permit independent judicial review of agency compliance with the Act without an affirmative statement to such effect, it could be argued that the absence of a prohibition on judicial review in title VII is indicative of an intent to permit judicial review similar to that permitted under the Regulatory Flexibility Act.

It is not clear, however, how judicial review is intended to operate in the context of risk assessments or regulatory impact analyses. What happens if the court finds that an agency failed to respond to a "significant" peer review comment (see section 3301(d)) or that the response was insufficient? Can the court stay the rule, or must the court find the rule to be arbitrary, capricious or otherwise an abuse of discretion as a result of the agency's failure?

What is the remedy if the agency incorrectly estimates the number of persons affected by the rule (section 7004(c)(9)), the paperwork burden imposed (section 7004(c)(13)), or the cost of agency implementation (section 7004(c)(21))? How will a court be expected to determine whether the agency satisfactorily demonstrated that the rule provides the least costly or least intrusive approach for meeting its intended purpose (section 7004(c)(7))?

7. The Department defers to other agencies with more expertise to evaluate whether the requirements of section 3105 are consistent with sound scientific principles.
8. Not applicable.
9. As a preliminary matter, and as noted in the letter transmitting these answers, the relationship between the peer review requirements of title III and regulatory impact analyses prepared pursuant to title VII is unclear. We believe, however, that title III is intended to apply only to major regulations affecting human health, safety, or the

environment (see especially sections 3101, 3103(b), 3201(a) and 3301(a)), and that title III does not authorize peer review of title VII regulatory impact analyses.

With respect to major regulations addressing human health, safety, or the environment, title III would appear to require the Department to convene separate peer review panels (or subpanels of a single panel) to review scientific information and economic/cost information developed with respect to a particular rulemaking. This is because scientific experts are not likely to have economic and cost assessment expertise, and vice-versa. Indeed, section 3301(c)(3) contemplates such separate reviews.

Section 3201(a) requires that a risk assessment be prepared for each major rule affecting human health, safety, or the environment. Assessments apply both to proposed and final rules, although the requirements are somewhat different. Unless an exception listed in section 3103(b)(2) applies, section 3301(b) appears to require that assessments be published with the rule or otherwise made available to the public at the time the rule is published.

The requirement for peer review does not appear applicable to proposed major rules affecting human health, safety or the environment (see section 3301(b), referencing section 3201(a)(5)(A)). Accordingly, the peer review requirements will not delay or prevent an agency from issuing a proposed regulation for comment.

Although title III does not specify whether a peer review, a peer review report, and/or the agency's response to the report must be completed prior to issuance of a final regulation subject to a risk assessment, this appears to be the intent of the title. This is because the principal purpose of a risk assessment is to enable agency policymakers to make informed decisions concerning rules and programs designed to protect human health, safety, or the environment. This conclusion is supported by the language of section 3301(e), which provides that peer review comments and conclusions, as well as the agency's responses to the peer review, be made part of the administrative record for judicial review of the underlying regulation.

While an agency presumably can identify outside experts and establish a peer review panel before a proposed rule is published or shortly thereafter, a panel probably cannot begin its review until the public comment period has closed and the agency has had an opportunity to assess the public comments and prepare the final rule. The amount of time it will take a panel to evaluate the regulation and prepare its report, and for an agency to prepare a written response to

the report, is likely to vary significantly depending on the subject matter and complexity of the rule. We assume that this process could be as short as a few weeks, or as long as several months or a year.

We believe that the Federal Advisory Committee Act (5 U.S.C. App.) (FACA) would apply to peer review panels in the absence of an explicit provision to the contrary (see FACA section 4(a)).

Application of FACA to peer review panels may not be appropriate. We note, for example, that section 3301(a) provides for the establishment of peer review panels consisting entirely of independent and external experts. FACA section 10(e), however, provides that an officer or employee of the Federal Government must chair or attend each meeting of an advisory committee, and that no committee shall conduct any business in the absence of that officer or employee. Similarly, FACA section 10(f) provides that advisory committees shall not hold any meetings except at the call of, and without an agenda approved by, such officer or employee.

Will the administrative requirements of FACA impose unintended burdens on peer review panels and impede their timely review of agency regulations and risk assessments? Should the charter provisions of FACA section 9(c) apply to peer review panels? Are peer review panel meetings intended to be open to the public (FACA section 10(a)(1)) and noticed in the *Federal Register* (FACA section 10(a)(2))? Are peer review panels expected to hear witnesses or accept statements from any interested person (FACA section 10(a)(3))? In addition to preparing peer review reports as described in section 3301(c), are peer review panels expected to keep detailed minutes of each meeting (FACA section 10(c))?

## TITLE III --INDEPENDENT SAFETY BOARD

## SHORT TITLE

49 USC 1901  
note

Sec. 301. This title may be cited as the "Independent Safety Board Act of 1974".

## FINDINGS

49 USC 1901.

Sec. 302. THE CONGRESS FINDS AND DECLARES:

(1) THE NATIONAL TRANSPORTATION SAFETY BOARD WAS ESTABLISHED BY STATUTE IN 1966 (Public Law 89-670; 80 Stat. 935) as an independent Government agency, located within the Department of Transportation, to promote transportation safety by conducting independent accident investigations and by formulating safety improvement recommendations.

49 USC 1654.

(2) Proper conduct of the responsibilities assigned to this Board requires vigorous investigation of accidents involving transportation modes regulated by other agencies of Government; demands continual review, appraisal, and assessment of the operating practices and regulations of all such agencies; and calls for the making of conclusions and recommendations that may be critical of or adverse to any such agency or its officials. No Federal agency can properly perform such functions unless it is totally separate and independent from any other department, bureau, commission, or agency of the United States.

## NATIONAL TRANSPORTATION SAFETY BOARD

49 USC 1902

Sec. 303. (a) ESTABLISHMENT.--The National Transportation Safety Board (hereinafter in this title referred to as the "Board"), previously established within the Department of Transportation, shall be an independent agency of the United States, in accordance with this section, on and after April 1, 1975.

Membership

(b) ORGANIZATION.--(1) The Board shall consist of five members, including a Chairman. Members of the Board shall be appointed by the President, by and with the advice and consent of the Senate. No more than three members of the Board shall be of the same political party. At any given time, no less than three members of the Board shall be individuals who have been appointed on the basis of technical qualification, professional standing, and demonstrated knowledge in the fields of accident reconstruction, safety engineering, human factors, transportation safety, or transportation regulation.

Term

(2) The terms of office of members of the Board shall be 5 years, except as otherwise provided in this paragraph. Any individual appointed to fill a vacancy occurring on the Board prior to the expiration of the term of office for which his predecessor was appointed shall be appointed for the remainder of that term. Upon the expiration of his term of office, a member shall continue to serve until his successor is appointed and shall have qualified. Individuals serving as members of the National Transportation Safety Board on the date of enactment of this title shall continue to serve as members of the Board until the expiration of their then current term of office. Any member of the Board may be removed by the President for inefficiency, neglect of duty, or malfeasance in office.

(3) On or before January 1, 1976 (and thereafter as required), the President shall --

(A) designate, by and with the advice and consent of the Senate, an individual to serve as the Chairman of the Board (hereafter in this title referred to as the "Chairman"); and

(B) an individual to serve as Vice Chairman.

The Chairman and Vice Chairman each shall serve for a term of 2 years. The Chairman shall be the chief executive officer of the Board and shall exercise the executive and administrative functions of the Board with respect to the appointment and supervision of personnel employed by the Board; the distribution of business among such personnel and among any administrative units of the Board; and the use and expenditure of funds. The Vice Chairman shall act as Chairman in the event of the absence or incapacity of the Chairman or in case of a vacancy in the office of Chairman. The Chairman or Acting Chairman shall be governed by the general policies established by the Board, including any decisions, findings, determinations, rules, regulations, and formal resolutions.

(4) Three members of the Board shall constitute a quorum for the transaction of any function of the Board.

(5) The Board shall establish and maintain distinct and appropriately staffed bureaus, divisions, or offices to investigate and report on accidents involving each of the following modes of transportation: (A) aviation; (B) highway and motor vehicle; (C) railroad and tracked vehicle; and (D) pipeline. The Board shall, in addition, establish and maintain any other such office as is needed, including an office to investigate and report on the safe transportation of hazardous materials.

(c) GENERAL.--(1) The General Services Administration shall furnish the Board with such offices, equipment, supplies, and services as it is authorized to furnish to any other agency or instrumentality of the United States.

(2) The Board shall have a seal which shall be judicially recognized.

(3) Subject to the civil service and classification laws, the Board is authorized to select, appoint, employ, and fix the compensation of such officers and employees, including investigators, attorneys, and administrative law judges, as shall be necessary to carry out its powers and duties under this title.

## GENERAL PROVISIONS

49 USC 1903.

## Sec. 304. (a) DUTIES OF BOARD.--The Board shall--

(1) investigate or cause to be investigated (in such detail as it shall prescribe), and determine the facts, conditions, and circumstances and the cause or probable cause or causes of any--

49 USC 1655.

(A) aircraft accident which is within the scope of the functions, powers, and duties transferred from the Civil Aeronautics Board under section 6(d) of the Department of Transportation Act (49 U.S.C. 1655(d)) pursuant to title VII of the Federal Aviation Act of 1958, as amended, (49 U.S.C. 1441);

(B) highway accident, including any railroad grade crossing accident, that it selects in cooperation with the States;

(C) railroad accident in which there is a fatality, substantial property damage, or which involves a passenger train;

(D) pipeline accident in which there is a fatality or substantial property damage;

(E) major marine casualty, except one involving only public vessels, occurring on the navigable waters or territorial seas of the United States, or involving a vessel of the United States, in accordance with regulations to be prescribed jointly by the Board and the Secretary of the department in which the Coast Guard is operating. Nothing in this subparagraph shall be construed to eliminate or diminish any responsibility under any other Federal statute of the Secretary of the department in which the Coast Guard is operating: *Provided*, That any marine accident involving a public vessel and any other vessel shall be investigated and the facts, conditions, and circumstances, and the cause or probable cause determined and made available to the public by either the Board or the Secretary of the Department in which the Coast Guard is operating; and

(F) other accident which occurs in connection with the transportation of people or property which, in the judgment of the Board, is catastrophic, involves problems of a recurring character, or would otherwise carry out the policy of this title.

Report.

Any investigation of an accident conducted by the Board under this paragraph (other than subparagraph (E)) shall have priority over all other investigations of such accident conducted by other Federal agencies. The Board shall provide for the appropriate participation by other Federal agencies in any such investigation, except that such agencies may not participate in the Board's determination of the probable cause of the accident. Nothing in this section impairs the authority of other Federal agencies to conduct investigations of an accident under applicable provisions of law or to obtain information directly from parties involved in, and witnesses to, the transportation accident. The Board and other Federal agencies shall assure that appropriate information obtained or developed in the course of their investigations is exchanged in a timely manner. The Board may request the Secretary of Transportation (hereafter in this title referred to as the "Secretary") to make investigations with regard to such accidents and to report to the Board the facts, conditions and circumstances thereof (except in accidents where misfeasance or nonfeasance by the Federal Government is alleged), and the Secretary or his designees are authorized to make such investigations. Thereafter, the Board, utilizing such reports, shall make its determination of cause or probable cause under this paragraph;

Report.

(2) report in writing on the facts, conditions, and circumstances of each accident investigated pursuant to paragraph (1) of this subsection and cause such reports to be made available to the public at reasonable cost;

(3) issue periodic reports to the Congress, Federal, State, and local agencies concerned with transportation safety, and other interested persons recommending and advocating meaningful responses to reduce the likelihood of recurrence of transportation accidents similar to those investigated by the Board and proposing corrective steps to make the transportation of persons as safe and free from risk of injury as is possible, including steps to minimize human injuries from transportation accidents;

(4) initiate and conduct special studies and special investigations on matters pertaining to safety in transportation including human injury avoidance;

(5) assess and reassess techniques and methods of accident investigation and prepare and publish from time to time recommended procedures for accident investigations;

(6) establish by regulation requirements binding on persons reporting (A) accidents and aviation incidents subject to the Board's investigatory jurisdiction under this subsection, and (B) accidents and aviation incidents involving public aircraft other than aircraft of the Armed Forces and the Intelligence Agencies;

(7) evaluate, assess the effectiveness, and publish the findings of the Board with respect to the transportation safety consciousness and efficacy in preventing accidents of other Government agencies;

(8) evaluate the adequacy of safeguards and procedures concerning the transportation of hazardous materials and the performance of other Government agencies charged with assuring the safe transportation of such materials; and

(9) review on appeal (A) the suspension, amendment, modification, revocation, or denial of any operating certificate or license issued by the Secretary of Transportation under sections 602, 609, or 611(c) of the Federal Aviation Act of 1958 (49 U.S.C. 1422, 1429, or 1431(c)) and the revocation of any certificate of registration under section 501(e)(2) of such Act; and (B) the decisions of the Commandant of the Coast Guard, on appeals from the orders of any administrative law judge revoking, suspending, or denying a license, certificate, document, or register in proceedings under section 4450 of the Revised Statutes of the United States (46 U.S.C. 239); the Act of July 15, 1954 (46 U.S.C. 239(a) and (b)); or section 4 of the Great Lakes Pilotage Act (46 U.S.C. 216(b)).

46 USC 239a, 239b.

46 USC 216b.

(b) POWERS OF BOARD.--(1) The Board, or upon the authority of the Board, any member thereof, any administrative law judge employed by or assigned to the Board, or any officer or employee duly designated by the Chairman, may, for the purpose of carrying out this title, hold such hearings, sit and act at such times and places, administer such oaths, and require by subpoena or otherwise the attendance and testimony of such witnesses and the production of such evidence as the Board or such officer or employee deems advisable.

Reports to  
Congress, Federal,  
State, and local  
agencies.

Subpoenas shall be issued under the signature of the Chairman, or his delegate, and may be served by any person designated by the Chairman. Witnesses summoned to appear before the Board shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. Such attendance of witnesses and production of evidence may be required from any place in the United States to any designated place of such hearing in the United States.

Inspections

(2) Any employee of the Board, upon presenting appropriate credentials and a written notice of inspection authority, is authorized to enter any property wherein a transportation accident has occurred or wreckage from any such accident is located and do all things therein necessary for a proper investigation, including examination or testing of any vessel, vehicle, rolling stock, track, or pipeline component or any part of any such item when such examination or testing is determined to be required for purposes of such investigation. Any examination or testing shall be conducted in such manner so as not to interfere with or obstruct unnecessarily the transportation services provided by the owner or operator of such vessel, vehicle, rolling stock, track, or pipeline component, and shall be conducted in such a manner so as to preserve, to the maximum extent feasible, any evidence relating to the transportation accidents, consistent with the needs of the investigation and with the cooperation of such owner or operator. The employee may inspect, at reasonable times, records, files, papers, processes, controls, and facilities relevant to the investigation of such accident. Each inspection, examination, or test shall be commenced and completed with reasonable promptness and the results of such inspection, examination, or test made available. The Board shall have sole authority to determine the manner in which testing will be carried out under this paragraph and under section 701(c) of the Federal Aviation Act of 1958, including determining the persons who will conduct the test, the type of test which will be conducted, and the persons who will witness the test. Such determinations are committed to the discretion of the Board and shall be made on the basis of the needs of the investigation being conducted by the Board and, where applicable, the provisions of this paragraph.

(3) In case of contumacy or refusal to obey a subpoena, an order, or an inspection notice of the Board, or of any duly designated employee thereof, by any person who resides, is found, or transacts business within the jurisdiction of any district court of the United States, such district court shall upon the request of the Board, have jurisdiction to issue to such person an order requiring such person to comply forthwith. Failure to obey such an order is punishable by such court as a contempt of court.

Contract  
authority

(4) The Board is authorized to enter into, without regard to section 3709 of the Revised Statutes of the United States (41 U.S.C. 5), such contracts, leases, cooperative agreements, or other transactions as may be necessary in the conduct of the functions and the duties of the Board under this title, with any government entity or any person.

Autopsy report

(5) The Board is authorized to obtain, and shall be furnished, with or without reimbursement, a copy of the report of the autopsy performed by State or local officials on any person who dies as a result of having been involved in a transportation accident within the jurisdiction of the Board and, if necessary, the Board may order the autopsy or seek other tests of such persons as may be necessary to the investigation of the accident: *Provided*, That to the extent consistent with the need of the accident investigation, provisions of local law protecting religious beliefs with respect to autopsies shall be observed.

(6) The Board is authorized to (A) use, on a reimbursable basis or otherwise, when appropriate, available services, equipment, personnel, and facilities of the Department of Transportation and of other civilian or military agencies and instrumentalities of the Federal Government; (B) confer with employees and use available services, records, and facilities of State, municipal, or local governments and agencies; (C) employ experts and consultants in accordance with section 3109 of title 5, United States Code; (D) appoint one or more advisory committees composed of qualified private citizens or officials of Federal, State, or local governments as it deems necessary or appropriate, in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 1); (E) accept voluntary and uncompensated services notwithstanding any other provision of law; (F) accept gifts or donations of money or property (real, personal, mixed, tangible, or intangible); (G) enter into contracts with public or private nonprofit entities for the conduct of studies related to any of its functions; and (H) require payment or other appropriate consideration from Federal agencies, and State, local, and foreign governments for the reasonable cost of goods and services supplied by the Board and to apply the funds received to the Board's appropriations.

State and local  
governments

Budget estimates,  
transmittal to  
Congress

(7) Whenever the Board submits or transmits any budget estimate, budget request, supplemental budget estimate, or other budget information, legislative recommendation, prepared testimony for congressional hearings, or comment on legislation to the President or to the Office of Management and Budget, it shall concurrently transmit a copy thereof to the Congress. No officer or agency of the United States shall have any authority to require the Board to submit its budget requests or estimates, legislative recommendations, prepared testimony for congressional hearings, or comment on legislation to any officer or agency of the United States for approval, comments, or review, prior to the submission of such recommendations, testimony, or comments to the Congress.

(8) The Board is empowered to designate representatives to serve or assist on such committees as the Chairman determines to be necessary or appropriate to maintain effective liaison with other Federal agencies, and with State and local government agencies, and with independent standard-setting bodies carrying out programs and activities related to transportation safety.

Publication in  
Federal Register.

(9) The Board, or an employee of the Board duly designated by the Chairman, may conduct an inquiry to secure data with respect to any matter pertinent to transportation safety, upon publication of notice of such inquiry in the Federal Register; and may require, by special or general orders, Federal, State, and local government agencies and persons engaged in the transportation of people or property in commerce to submit written reports and answers to such requests and questions as are propounded with respect to any matter pertinent to any function of the Board. Such reports and answers shall be submitted to the Board or to such

employee within such reasonable period of time and in such form as the Board may determine. Copies thereof shall be made available for inspection by the public.

(10) The Board may at any time utilize on a reimbursable basis the services of the Transportation Safety Institute of the Department of Transportation (established for the purpose of developing courses and conducting training in safety and security for all modes of transportation) or any successor organization. The Secretary shall continue to make available such Institute or successor organization (A) to the Board for safety training of employees of the Board in the performance of all of their authorized functions, and (B) to such other safety personnel of Federal, interstate, State, local, and foreign governments and non-governmental organizations as the Board may from time to time designate in consultation with the Secretary. Utilization of such training at the Institute or successor organization by any designated non-Federal safety personnel shall be at a reasonable fee to be established periodically by the Board in consultation with the Secretary. Such fee shall be paid directly to the Secretary for the credit of the proper appropriation, subject to the requirements of any annual appropriation, and shall be an offset against any annual reimbursement agreement entered into between the Board and the Secretary to cover all reasonable direct and indirect costs incurred for all such training by the Secretary in the administration and operation of the Institute or successor organization. The Board shall maintain an annual record of all such offsets. In providing such training to Federal employees, the Board shall be subject to chapter 41 of title 5, United States Code (relating to training of employees).

(11)(A) Notwithstanding section 503(e) of the Act entitled "An Act making supplemental appropriations for the fiscal year ending September 30, 1987, and for other purposes", approved July 11, 1987 (5 U.S.C. 7301 note), the Board is authorized to obtain from the Secretary of Transportation, by written request, and shall be furnished --

(i) any report of a confirmed positive toxicological test, verified as positive by a medical review officer, which is conducted on an employee of the Department of Transportation, including any of its agencies, pursuant to post-accident, unsafe practice, or reasonable suspicion toxicological testing requirements of the Department, when that employee is reasonably associated with the circumstances of an accident or incident within the investigative jurisdiction of the Board; and

(ii) any laboratory record providing documentation that such test is confirmed positive.

(B) Except as provided in subparagraph (C), the Board shall maintain in confidence and exempt from public disclosure in accordance with section 552(b)(3) of title 5, United States Code--

(i) any laboratory record, made available under subparagraph (A), of a confirmed and verified toxicological test which reveals medical use of a drug permitted under applicable regulations; and

(ii) any medical information provided by the tested employee in connection with such test or in connection with a review of such test.

(C) The Board may use such a laboratory record for development of any evidentiary record in an investigation by the Board of an accident or incident if--

(i) the fitness of the employee who is the subject of the toxicological testing is at issue in the investigation; and

(ii) the use of the record is necessary in the development of such evidentiary record.

(12) Establish such rules and regulations as may be necessary to the exercise of its functions

(c) **USE OF REPORTS AS EVIDENCE.**--No part of any report of the Board, relating to any accident or the investigation thereof, shall be admitted as evidence or used in any suit or action for damages growing out of any matter mentioned in such report or reports.

(d) **JUDICIAL REVIEW.**--Any order, affirmative or negative, issued by the Board under this title shall be subject to review by the appropriate court of appeals of the United States or the United States Court of Appeals for the District of Columbia, upon petition filed within 60 days after the entry of such order, by any person disclosing a substantial interest in such order. Such review shall be conducted in accordance with the provisions of chapter 7 of title 5, United States Code.

#### ANNUAL REPORT

Sec. 305. The Board shall report to the Congress on July 1 of each year. Such report shall include, but need not be limited to--

(1) a statistical and analytical summary of the transportation accident investigations conducted and reviewed by the Board during the preceding calendar year;

(2) a survey and summary, in such detail as the Board deems advisable, of the recommendations made by the Board to reduce the likelihood of recurrence of such accidents together with the observed response to each such recommendation;

(3) an appraisal in detail of the accident investigation and accident prevention activities of other government agencies charged by Federal or State law with responsibility in this field; and

(4) a biennial appraisal and evaluation and review, and recommendations for legislative and administrative action and change, with respect to transportation safety.

#### PUBLIC ACCESS TO INFORMATION

Sec. 306. (a) **GENERAL.**--Copies of any communication, document, investigation, or other report, or information received or sent by the Board, or any member or employee of the Board, shall be made available to the public upon identifiable request, and at reasonable cost, unless such information may not be publicly released pursuant to subsection (b) or (c) of this section. Nothing contained in this section shall be deemed to require the release of any information described by subsection (b) of section 552 of title 5, United States Code, or which is otherwise protected by law from disclosure to the public.

Information  
disclosure,  
prohibition.

(b) EXCEPTION.--The Board shall not disclose information obtained under this title which concerns or relates to a trade secret referred to in section 1905 of title 18, United States Code, except that such information may be disclosed in a manner designed to preserve confidentiality--

(1) upon request, to other Federal Government departments and agencies for official use;

(2) upon request, to any committee of Congress having jurisdiction over the subject matter to which the information relates;

(3) in any judicial proceeding under a court order formulated to preserve the confidentiality of such information without impairing the proceedings; and

(4) to the public in order to protect health and safety, after notice to any interested person to whom the information pertains and an opportunity for such person to comment in writing, or orally in closed session, on such proposed disclosure (if the delay resulting from such notice and opportunity for comment would not be detrimental to health and safety).

(c) Public Disclosure of Cockpit Voice Recorder Recordings and Transcriptions.--(1) Notwithstanding any other provision of law, the Board shall withhold from public disclosure cockpit voice recorder recordings and transcriptions, in whole or in part, of oral communications by and between flight crew members and ground stations, that are associated with accidents or incidents investigated by the Board.

(2) Portions of a transcription of oral communications described in paragraph (1) which the Board determines relevant and pertinent to the accident or incident under investigation shall be made available to the public by the Board--

(A) if the Board conducts a public hearing with respect to such accident or incident, at the time of such hearing; and

(B) if the Board does not conduct such a public hearing, at the time when a majority of other factual reports regarding the accident or incident is placed in the public docket.

(3) Nothing in this section shall restrict the Board at any time from referring to cockpit voice recorder information in making safety recommendations.

(d) Use of Cockpit Voice Recorder Recordings and Transcriptions in Judicial Proceedings.--(1) Except as provided in this subsection, in a judicial proceeding, there shall not be discovery by a party--

(A) of portions of cockpit voice recorder transcriptions other than such portions made available to the public by the Board under subsection (c)(2); and

(B) of cockpit voice recorder recordings.

(2) Subject to paragraph (4), a court may permit discovery of cockpit voice recorder transcriptions by a party if the court, after an in camera review of such transcriptions, finds that--

(A) the portions of the transcriptions made available to the public under subsection (c) do not provide the party with sufficient information for the party to receive a fair trial; and

(B) discovery of additional portions of transcriptions is necessary to provide the party with sufficient information for the party to receive a fair trial.

No cockpit voice recorder transcriptions prepared by or under the direction of the Board, other than portions made available by the Board under subsection (c), shall be required to be produced for an in camera review, or shall be subject to discovery, unless the cockpit voice recorder recordings are not available.

(3) Subject to paragraph (4), a court may permit discovery of cockpit voice recorder recordings by a party if the court, after an in camera review of such recordings, finds that--

(A) the portions of transcriptions made available to the public under subsection (c) and to the party through discovery under paragraph (2) do not provide the party with sufficient information for the party to receive a fair trial; and

(B) discovery of cockpit voice recorder recordings is necessary to provide the party with sufficient information for the party to receive a fair trial.

(4) If, under paragraph (2) or (3), there is discovery in a judicial proceeding of a cockpit voice recorder recording or any portion of a cockpit voice recorder transcription not made available to the public under subsection (c)(2), the court shall issue a protective order to limit the use of such recording or portion to the judicial proceeding and to prohibit dissemination of such recording or portion to any person who does not need access to such recording or portion for such proceeding.

(5) A court may permit admission of a cockpit voice recorder recording or any portion of a cockpit voice recorder transcription not made available to the public under subsection (c)(2) into evidence in a judicial proceeding, only if the court places such recording or portion under seal to preclude the use of such recording or portion for purposes other than for such proceeding.

#### RESPONSE TO BOARD RECOMMENDATIONS

49 USC 1906.

Sec. 307(a). Whenever the Board submits a recommendation regarding transportation safety to the Secretary, he shall respond to each such recommendation formally and in writing not later than 90 days after receipt thereof. The response to the Board by the Secretary shall indicate his intention to--

(1) initiate and conduct procedures for adopting such recommendation in full, pursuant to a proposed timetable, a copy of which shall be included;

(2) initiate and conduct procedures for adopting such recommendation in part, pursuant to a proposed timetable, a copy of which shall be included. Such response shall set forth in detail the reasons for the refusal to proceed as to the remainder of such recommendation; or

(3) refuse to initiate or conduct procedures for adopting such recommendation. Such response shall set forth in detail the reasons for such refusal.

The Board shall make copies thereof available to the public at reasonable cost.

Report to  
Congress

(b) The Secretary shall submit a report to the Congress on January 1 of each year setting forth all the Board's recommendations to the Secretary during the preceding year regarding transportation safety and a copy of the Secretary's response to each such recommendation.

#### CONFORMING AMENDMENTS

Sec. 308. The Department of Transportation Act is amended--

(1) by deleting section 5 (49 U.S.C. 1654);

(2) by amending section 4(c) thereof (49 U.S.C. 1653(c)) by deleting "or the National Transportation Safety Board" in the first sentence thereof; and by deleting in the second sentence thereof ", the Administrators, or the National Transportation Safety Board." and by inserting in lieu thereof "or the Administrators."; and

(3) by amending section 4(d) thereof (49 U.S.C. 1653(d)) by deleting ", the Administrators, and the National Transportation Safety Board" and by inserting in lieu thereof "and the Administrators".

#### AUTHORIZATION OF APPROPRIATIONS

Sec. 309(a). There are authorized to be appropriated for the purposes of this Act not to exceed \$32,000,000 for the fiscal year ending September 30, 1991; \$38,600,000 for the fiscal year ending September 30, 1992; and \$38,800,000 for fiscal year ending September 30, 1993. Such sums shall remain available until expended.

(b) An emergency fund of \$1,000,000 is authorized for expenditure by the Board to be available for necessary expenses, not otherwise provided for, of the Board for accident investigations. There is authorized to be appropriated such sums as may be necessary to establish the emergency fund under the preceding sentence and to replenish the fund annually. Such sums are authorized to remain available until expended.

Public Law 93-633, January 3, 1975 as amended by:

Pub. L. 97-74, November 3, 1981;

Pub. L. 97-309, October 14, 1982;

Pub. L. 98-499, October 19, 1984;

Pub. L. 100-223, December 30, 1987;

Pub. L. 100-372, July 19, 1988;

Pub. L. 101-641, November 28, 1990.

**Federal Aviation Act of 1958  
as Amended**

**TITLE VII--AIRCRAFT ACCIDENT INVESTIGATION**

**ACCIDENTS INVOLVING CIVIL AIRCRAFT**

GENERAL DUTIES

Sec. 701. [49 U.S.C. 1441](a) It shall be the duty of the National Transportation Safety Board to --

- (1) Make rules and regulations governing notification and report of accidents involving civil aircraft;
- (2) Investigate such accidents and report the facts, conditions, and circumstances relating to each accident and the probable cause thereof;
- (3) Make such recommendations to the Secretary of Transportation as, in its opinion, will tend to prevent similar accidents in the future;
- (4) Make such reports public in such form and manner as may be deemed by it to be in the public interest; and
- (5) Ascertain what will best tend to reduce or eliminate the possibility of, or recurrence of, accidents by conducting special studies and investigations on matters pertaining to safety in air navigation and the prevention of accidents.

TEMPORARY PERSONNEL

(b) The National Transportation Safety Board may, without regard to the civil-service laws, engage, for temporary service in the investigation of any accident involving aircraft, persons other than officers or employees of the United States and may fix their compensation without regard to the Classification Act of 1949, as amended [chapter 51 and subchapter III of chapter 53 of title 5]; and may, with consent of the head of the executive department or independent establishment under whose jurisdiction the officer or employee is serving, secure for such service any officer or employee of the United States.

CONDUCT OF INVESTIGATIONS

(c) In conducting any hearing or investigation, any member of the National Transportation Safety Board or any officer or employee of the National Transportation Safety Board or any person engaged or secured under subsection (b) shall have the same powers as the National Transportation Safety Board has with respect to hearings or investigations conducted by it. In carrying out its duties under this title, the National Transportation Safety Board is authorized to examine and test to the extent necessary any civil aircraft, aircraft engine, propeller, appliance, or property aboard an aircraft involved in an accident in air commerce. In the case of any fatal accident, the National Transportation Safety Board is authorized to examine the remains of any deceased person aboard the aircraft at the time of the accident, who dies as a result of the accident, and to conduct autopsies or such other tests thereof as may be necessary to the investigation of the accident; *Provided*, That to the extent consistent with the needs of the accident investigation, provisions of local law protecting religious beliefs with respect to autopsies shall be observed. [Subsection (c) as amended by Public Law 87-810, 87th Congress, 2nd Session, approved October 15, 1962, 76 Stat. 921.]

AIRCRAFT

(d) Any civil aircraft, aircraft engine, propeller, appliance, or property aboard an aircraft involved in an accident in air commerce, shall be preserved in accordance with and shall not be moved except in accordance with, regulations prescribed by the National Transportation Safety Board. [Subsection (d) as amended by Public Law 87-810, 87th Congress, 2nd Session, approved October 15, 1962, 76 Stat. 921.]

USE OF RECORDS AND REPORTS AS EVIDENCE

(e) No part of any report or reports of the National Transportation Safety Board relating to any accident or the investigation thereof, shall be admitted as evidence or used in any suit or action for damages growing out of any matter mentioned in such report or reports.

USE OF SECRETARY OF TRANSPORTATION  
IN ACCIDENT INVESTIGATIONS

(f) Upon the request of the National Transportation Safety Board, the Secretary of Transportation is authorized to make investigations with regard to aircraft accidents and to report to the National Transportation Safety Board the facts, conditions, and circumstances thereof, and the National Transportation Safety Board is authorized to utilize such reports in making its determination of probable cause under this subchapter.

PARTICIPATION BY SECRETARY OF TRANSPORTATION

(g) In order to assure the proper discharge by the Secretary of Transportation of his duties and responsibilities, the National Transportation Safety Board shall provide for the appropriate participation of the Secretary of

Transportation and his representatives in any investigations conducted by the National Transportation Safety Board under this title. *Provided*, That the Secretary of Transportation or his representatives shall not participate in the determination of probable cause by the National Transportation Safety Board under this title.

**Note:** The above text, in conformity with the U.S. Code, reflects the transfer of functions from the Federal Aviation Agency to the Secretary of Transportation pursuant to Pub. L. 89-670. "National Transportation Safety Board" was substituted for "Board" pursuant to Pub. L. 93-633.

#### ACCIDENTS INVOLVING MILITARY AIRCRAFT

Sec. 702. [49 U.S.C. 1442] (a) In the case of accidents involving both civil and military aircraft, the National Transportation Safety Board shall provide for participation in the investigation by appropriate military authorities.

(b) In the case of accidents involving solely military aircraft and in which a function of the Secretary of Transportation is or may be involved, the military authorities shall provide for participation in the investigation by the Secretary of Transportation.

(c) With respect to other accidents involving solely military aircraft, the military authorities shall provide the Secretary of Transportation and the National Transportation Safety Board with any information with respect thereto which, in the judgment of the military authorities, would contribute to the promotion of air safety.

**Note:** The above text, in conformity with the U.S. Code, reflects the transfer of functions from the Federal Aviation Agency to the Secretary of Transportation pursuant to Pub. L. 89-670. "National Transportation Safety Board" was substituted for "Board" pursuant to Pub. L. 93-633.

#### SPECIAL BOARDS OF INQUIRY

Sec. 703. [49 U.S.C. 1443] (a) In any accident which involves substantial questions of public safety in air transportation the National Transportation Safety Board may establish a Special Board of Inquiry consisting of three members; one member of the National Transportation Safety Board who shall act as Chairman of the Special Board of Inquiry; and two members representing the public who shall be appointed by the President upon notification of the creation of such Special Board of Inquiry by the National Transportation Safety Board.

(b) Such public members of the Special Board of Inquiry shall be duly qualified by training and experience to participate in such inquiry and shall have no pecuniary interest in any aviation enterprise involved in the accident to be investigated.

(c) The Special Board of Inquiry when convened to investigate an accident certified to it by the National Transportation Safety Board shall have all authority of the National Transportation Safety Board as described in this title.

**Note:** In the above text, "National Transportation Safety Board" was substituted for "Board" and for "Civil Aeronautics Board" pursuant to the transfers of functions contained in Public Laws 89-670 and 93-633.



## THE SECRETARY OF VETERANS AFFAIRS

WASHINGTON

FEB 3 1995

The Honorable Robert S. Walker  
Chairman, Committee on Science  
U.S. House of Representatives  
Washington, DC 20515

Dear Mr. Chairman:

This concerns your request for information about VA's risk assessment activities of the type referred to in Title III of H.R. 9, a bill known as the "Job Creation and Wage Enhancement Act of 1995."

We note that Title III only concerns activities relating to "Federal regulatory programs designed to protect human health, safety, or the environment." The Department of Veterans Affairs does not regularly issue regulations pertaining to the above subjects. Rather, VA regulations pertain to providing Congressionally mandated benefits to veterans. Generally, any regulations promulgated by VA pertaining to health care relate only to care provided by VA to veterans or their dependents. Thus, the VA does not conduct risk assessments that would be affected by Title III. Under these circumstances, we do not have any information to report in response to your request.

The Office of Management and Budget advises that there is no objection from the standpoint of the Administration's program to the submission of this report on H.R. 9 to the Congress.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Jesse Brown".

Jesse Brown

JB/tog



## THE SECRETARY OF VETERANS AFFAIRS

WASHINGTON

FEB 1 1995

The Honorable George E. Brown, Jr.  
 Committee on Science  
 Ranking Minority Member  
 U.S. House of Representatives  
 Washington, DC 20515

Dear Congressmen Brown:

This is in response to your request for our comments on H.R. 9. Our understanding of H.R. 9 is that it would significantly modify the existing process for issuing regulations intended to protect human health, safety and the environment. The Department of Veterans Affairs does not regularly issue regulations pertaining to the above subjects. Rather, VA regulations pertain to providing Congressionally mandated benefits to veterans. Generally, any regulations promulgated by VA pertaining to health care relate only to care provided by VA to veterans or their dependents. Thus, we do not believe that this legislation would have significant impact on VA's regulatory activity.

It would be extremely difficult to predict what VA regulations we would expect to propose or promulgate in the next two years because VA regulations are tied to legislation.

However, we have reviewed the proposed legislation and provide the following comments on Titles III and VII.

Title III has little, if any, applicability to the promulgation of VA regulations. The purpose of the Department of Veterans Affairs is to administer veterans benefits, as set out in statutes. VA is not a regulatory agency whose purpose is to issue rules affecting the public health, safety or environment.

Title VII would impose additional rule making publication requirements; additional analyses; and additional OMB detailed reviews. In our view, these additional requirements are too costly and resource intensive for any perceived benefits. Further, this would delay the promulgation of VA regulations, including those affecting health care benefits, education benefits and compensation benefits. Had this provision been in effect at the time of regulations written for distribution of homeless veterans grants and for the provision of benefits to Persian Gulf veterans, these programs would have been considerably delayed. It is difficult to see what useful purpose would be served in denying veterans benefits for a period of time, merely to allow additional periods of comment and additional analyses

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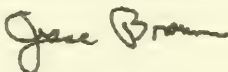
The Honorable George E. Brown, Jr.

of the proposed regulations. The Department currently communicates with Veterans Service Organizations during the regulatory creation process so as to be responsive to the concerns of the organized veterans community. The delays built into the process as provided in Title VII would merely add to the bureaucratic nature of the regulation writing process.

The Office of Management and Budget advises that there is no objection from the standpoint of the Administration's program to the submission of this report on H.R. 9 to the Congress.

We hope this responds to your inquiry.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Jesse Brown". The signature is fluid and cursive, with the first name "Jesse" written in a larger, more prominent script than the last name "Brown".

Jesse Brown

JB/nsr

cc: The Honorable Robert Walker, Chairman



## Federal Emergency Management Agency

Washington, D.C. 20472

FEB 2 - 1995

The Honorable George E. Brown, Jr.  
 Ranking Minority Member  
 Committee on Science  
 U.S. House of Representatives  
 Washington, DC 20515

Dear Mr. Brown:

Thank you for your letter of January 20, 1995, requesting the Federal Emergency Management Agency's (FEMA) comments on Titles III and VII of H.R. 9, the Job Creation and Wage Enhancement Act of 1995. I would like to offer some general comments about Titles III and VII, and then answer the specific questions you asked.

As presently written, the language of Title III is so general that it is difficult to interpret definitively whether it applies, does not apply, or is intended to apply to FEMA's disaster and emergency assistance, flood insurance, mitigation, and fire prevention programs. The sense of the Title seems to be that it does not apply to our programs, and we would interpret it that way. However, as drafted some might interpret it to apply to our programs.

Title III appears to be concerned primarily with the assessment of chemical and biological threats to public health, safety, and the environment, and to the appropriate way to assess impacts of applicable Federal regulations on businesses and on the public health. FEMA assesses the cost effectiveness of its mitigation measures and the vulnerability of property to natural and other hazards or events (fires, floods, earthquakes, hurricanes). Our cost effectiveness assessments are akin to actuarial analyses because we must assess the probability of damages from various natural events. While we use principles and methodologies asserted in Title III, our use and application of risk assessment and cost-benefit analyses are different from those addressed in the legislation.

As the legislation progresses, it would be desirable for all concerned that the applicability of Title III be clearly defined, and that the legislation include exemptions. FEMA is not a regulatory agency in the sense of a Federal agency given regulatory authority to monitor and oversee a segment of the economy, e.g., the Securities and Exchange Commission. Nor does FEMA conduct or sponsor primary research on risk, or collect new

or generic data for grant purposes.

Our regulations derive from and respond to Congressional mandates for disaster relief and emergency assistance, for prevention and reduction of the costs of disasters, for insurance against flood losses and appropriate measures to reduce flood and other disaster losses, for planning, training and exercises in emergency preparedness, and for fire prevention and control.

Under the Act's proposed redefinition of "major rule", Title VII would affect a high percentage of FEMA's disaster response and recovery, flood insurance, floodplain management, hazard mitigation, special projects, and other related emergency management programs. Title VII would expand the applicability of regulatory analysis by redefining "major rule" at a threshold significantly lower than the threshold for "significant regulatory actions" currently in force under E.O. 12866. It would increase the time required for rulemaking with additional notice requirements. It would add costs to FEMA rulemaking with at least 23 new explanations, descriptions, statements, estimates, demonstrations, and evaluations, among other things. To the extent that agency actions are judicially reviewable and new requirements are added, it would appear that judicial review would extend beyond what is presently permitted under the Administrative Procedure Act.

The Office of Management and Budget advises that there is no objection to submission of this report from the perspective of the President's program.

Thank you for your inquiry. If you need additional information please ask your staff to contact our Office of Congressional and Governmental Affairs at 646-4500.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Harvey G. Ryland', written in a cursive style.

Harvey G. Ryland  
Deputy Director

## QUESTIONS

1. Please identify the programs in the Agency which would be subject to the requirements of the Risk Assessment and Communication Act of 1995 (Title III of H.R. 9), taking into account Title VII and other relevant sections of H.R.9.

A. FEMA cannot define the scope of Title III as it is presently written, and, therefore, cannot identify what programs, if any, would be subject to the requirements of Title III if H.R. 9 were enacted.

2. Using the definitions of "risk assessment" and "risk characterizations" set out in section 3107 of the Act, how many risk assessments and risk characterizations were prepared by, or on behalf of, the programs in the Agency over the last fiscal year? Of those, how many would be considered to be a "screening analysis" exempted under Section 3103(b)(2)?

A. No risk assessments, risk characterizations, or screening analyses were prepared by, or on behalf of, the programs in FEMA, over the last fiscal year, using the definitions set out in § 3107 of H.R. 9.

3. Please describe the Agency's present practices, including references to any published guidelines or procedures, relating to risk assessment, risk characterization, cost-benefit analysis, or peer review.

A. FEMA's Mitigation Directorate uses an interim guide, "Cost-Effectiveness Assessment of Hazard Mitigation Projects", including software, to analyze the costs and benefits of projects funded under either § 404 or § 406 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), as amended, 42 U.S.C. §§ 5170c, 5172. Our use of benefit-cost analysis is only in connection with grants administration, i.e., Stafford Act mandates to provide grants only for "cost-effective" mitigation projects.

4. If enacted into law, how would the Act affect the Agency's present practices as described in question 3? If compliance with the Act would require additional resources in carrying out such practices, please estimate the additional resources (in terms of dollars and personnel) that would be required to carry out the provisions of the Act.

A. If enacted into law and if applicable to FEMA's programs, the Act would require FEMA to expand its analyses to include formal risk assessment, risk characterization, and peer review, none of which currently apply to FEMA

programs as defined by the Act. We estimate that an additional 10 FTE and \$600,000 per year would be required to meet our needs under current programs if H.R. 9 were enacted and it applied to FEMA programs.

5. How does the Agency obtain the information it uses to prepare risk assessments, cost-benefit analyses, or risk characterizations? Does the Agency rely in part upon the private sector in providing the information needed by the Agency to conduct such assessments or analyses? If so, would the Act require the Agency to obtain additional information from the private sector in order to comply with the Act's requirements?

A. We use our own personnel, or through mission assignments we may give other agencies tasks to collect data, and those agencies may contract with engineering or other groups. We collect existing data such as the hydraulics of stream flow, or the known seismic risk, or the return frequency of hurricane winds in a designated disaster area. These and other data are relevant to our assessment of the cost-effectiveness of mitigation measures, i.e., to avoid future damages to property from flooding, earthquakes, or other disasters. If FEMA's programs were included within the scope of H.R. 9, we anticipate that we would incur significant additional costs and would need to obtain information in addition to the information that we gather already.

6. Please identify the regulations expected to be proposed or promulgated in the next two years which would require a Regulatory Impact Analysis under Title VII, an analysis of risk reduction benefits and costs or a certification under Subtitle B of Section 3201, or a peer review under Section 3301. What additional procedures would the Agency be required to follow to issue such regulations if the Act were enacted into law? Would the Act permit judicial review of agency actions beyond what is presently permitted under the Administrative Procedure Act? Please estimate the additional time and resources that would be necessary to complete the expected rulemaking following the required procedures. If the Agency is subject to court-ordered or statutory deadlines for completion of any such regulations, can the Agency comply with the Act and still meet such deadlines?

A. Under the Act's proposed redefinition of "major rule", Title VII would affect a high percentage of FEMA's disaster response and recovery, flood insurance, floodplain management, hazard mitigation, special projects, and other related emergency management programs. Title VII would expand the applicability of regulatory analysis by redefining "major rule" at a threshold significantly lower than the threshold for "significant regulatory actions" currently in force under E.O. 12866. It would increase the

time required for rulemaking with additional notice requirements. It would add costs to FEMA rulemaking with at least 23 explanations, descriptions, statements, estimates, demonstrations, and evaluations, among other things. To the extent that agency actions are judicially reviewable and new requirements are added, it would appear that judicial review would extend beyond what is presently permitted under the Administrative Procedure Act.

FEMA currently lists over 20 proposed and final regulatory actions in the October 1994 semi-annual Unified Agenda of Federal Regulations. Very few of the rules listed are "significant regulatory actions" under E.O. 12866. Almost all of them would be "major rules" under Title VII definitions. If the rulemaking workload remained at current levels, we could anticipate that the time and effort entailed to complete that workload could increase tenfold.

FEMA has one court-ordered deadline at present, and several 180-day and 270-day statutory deadlines. We estimate that none of them could be met under the Act if enacted as presently written and made applicable to FEMA.

7. Are the requirements of section 3105 for risk characterization (taking into account the definitions in 3106) consistent with the Agency's understanding of sound scientific principles for risk assessment and risk characterization? Would the requirements of section 3105 preclude the Agency from considering any information, models, or assumptions in assessing or characterizing risk? How would the Agency be able to take into account risks to special subpopulations which may have higher susceptibility than "average"?

A. Title III appears to be concerned primarily with the assessment of chemical and biological threats to public health, safety, and the environment, and to the appropriate way to assess impacts of applicable Federal regulations on businesses and on the public health. FEMA assesses the cost effectiveness of its mitigation measures and the vulnerability of property to natural and other hazards or events (fires, floods, earthquakes, hurricanes). While we use principles and methodologies asserted in Title III, our use and application of risk assessment and cost-benefit analyses are different from those addressed in the legislation.

8. To the extent not already addressed in previous answers, please identify all risk assessment documents, regulatory proposals or decisions, reports to Congress, or other documents made available to the public by the Agency which include characterizations of risks that would be subject to the requirements of section 3105.

A. Please see the previous answers.

9. Please estimate the cost of complying with the peer review requirements of section 3301, taking into account the provisions of Title VII requiring Regulatory Impact Analyses. How would the Agency implement the requirement for peer review of "economic assessments", "economic information," and "cost assessments"? Would the Agency be precluded from issuing any regulation until the required peer review, peer review report, and response to the peer review, had been completed and made available to the public? How long would such a process be likely to take? Would such peer review panels be subject to the Federal Advisory Committee Act?

A. If H.R. 9 were applicable to FEMA, we estimate that the annual cost to FEMA of complying with the peer review requirements of section 3301 would range between \$100,000 and \$200,000. Relatively few FEMA regulations would meet the threshold criteria for major rules subject to peer review. We estimate that perhaps 2 - 3 professional years of effort, plus expenses, would be required to comply annually. Outside professionals would have to be retained by contract, given adequate time to review the assessments and information, and to prepare individual reports. Peer review panels may or may not be subject to the Federal Advisory Committee Act, but statutory exemption or inclusion could clarify Congressional intent.

Mr. BROWN. And, Mr. Chairman, I ask that the record be left open for a reasonable time to allow submissions from several other departments which I have not yet received but which I am told are on their way.

The CHAIRMAN. Without objection.

[The information follows:]

## U.S. DEPARTMENT OF LABOR

SECRETARY OF LABOR  
WASHINGTON, D.C.

ECR 3 1995

The Honorable George E. Brown, Jr.  
 Ranking Minority Member  
 Committee on Science  
 U.S. House of Representatives  
 Washington, D. C. 20515

Dear Congressman Brown:

I appreciate the opportunity to respond to your questions about the risk assessment provisions of H.R. 9, the Job Creation and Wage Enhancement Act. This Act is of concern to the Department of Labor (DOL) because, if passed, it would adversely alter the rulemaking process of this Department's agencies. The Act requires additional steps in the rulemaking process that would reduce DOL's ability to respond efficiently and effectively in protecting America's workers.

The Title III requirements pertaining to risk assessment and risk characterization are of particular concern because of the impact on three of our agencies: the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), and the Employment Standards Administration (ESA), which promulgate rules regarding occupational safety and health, mining safety and health, and child labor, respectively. Title III of H.R. 9 would not only require MSHA and ESA to create a complicated risk assessment structure to supplement their current risk analyses, but would negatively impact and fundamentally alter OSHA's rulemaking process.

The Department believes that risk analysis is a necessary and appropriate tool for linking sound policy decisions with sound science. For example, OSHA has nearly 15 years of experience conducting effective and reasonable risk analyses to support regulation. These risk assessments have helped OSHA ensure that the health and safety of American workers are protected while simultaneously ensuring that its rules are both economically reasonable and scientifically sound.

In developing its risk assessments for toxic substances, hazardous physical agents, and safety hazards, OSHA follows established scientific principles and nationally recognized guidelines, such as those of the National Academy of Sciences. For health standards, OSHA also carefully explains and justifies its choice of risk assessment models and discusses the weight of the evidence in a comprehensive manner. For safety standards, OSHA also describes all relevant injury and fatality data and any other information relevant to the assessment of risk. OSHA takes these steps to ensure that its risk assessments and risk

characterizations are as clear and understandable as possible. OSHA also invites comment on all aspects of its risk assessments at the proposal, public hearing, and final rule stages of standards development.

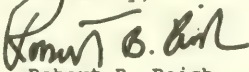
The Department's principal concern with Title III of H.R. 9 is that it would be harmful to America's working men and women because it would create a procedural obstacle course for OSHA's risk assessment process and would prevent the more flexible case-by-case approach now in use. The resulting lengthy and unproductive delays will jeopardize the Department's ability to protect workers from hazards in a timely fashion. In addition, Title III would require MSHA and ESA to develop and implement cumbersome risk assessment procedures in addition to any regulatory impact analyses the agencies currently conduct.

Although the Department supports much of the thrust of H.R. 9, our agencies need the capacity to use risk assessment effectively, efficiently and creatively. We believe that H.R. 9 will impose overly costly, burdensome, and time-consuming risk assessment processes, together with similarly excessive and detrimental judicial review, which will severely reduce the Department's ability to timely and effectively protect workers. We believe that the bill will decrease flexibility and limit the Department's ability to respond effectively. These consequences also have a human side: increased numbers of preventable fatalities, injuries, and illnesses among America's workers.

The Department supports risk assessment legislation that encourages the use of risk assessment principles, techniques, and procedures that are fair, consistent, effective, and economically reasonable and will enhance the Department's ability to issue regulations that protect American workers.

The enclosed responses to your questions clarify our concerns.

Sincerely,

A handwritten signature in dark ink, appearing to read "Robert B. Reich", written in a cursive style.

Robert B. Reich

Enclosure

Enclosure  
DOL Responses to Questions  
on Risk Assessment  
from Rep. George E. Brown, Jr.,  
Ranking Minority Member,  
House Committee on Science

Questions:

1. Please identify the programs in the Department which would be subject to the requirements of the Risk Assessment and Communication Act of 1995 (Title III of H.R. 9), taking into account Title VII and other relevant sections of H.R. 9.

There are three Labor Department agencies which would be subject to the requirements of the Risk Assessment and Communication Act of 1995 (Title III of H.R.9): the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), and the Employment Standards Administration (ESA), which promulgates and enforces rules regarding child labor hazardous occupations.

While the risk assessment requirements of Title III of H.R. 9 would only apply to these three agencies of DOL, the requirements contained in Title VII and other relevant sections of H.R. 9 are much broader and would affect the rulemaking process of all DOL's agencies. In particular, Section 7004 of Title VII changes the definition of a "major rule", thereby broadening Federal regulatory requirements and requirements for regulatory impact analysis to include: any proposed regulatory action which (1) affects more than 100 persons or (2) compliance with which will require the expenditure of more than \$1,000,000. In addition, this section requires the regulatory impact analysis to include detailed explanations, descriptions and economic and paperwork burden cost estimates regarding the regulations.

The impact of the change in the definition of "major rule" will mean that many regulations which have traditionally not been considered major rules, such as Black Lung and Longshore regulations, would most likely not be exempt from the additional rulemaking requirements. The rulemaking requirements themselves are also significantly expanded and would make the process so burdensome that few regulations would be issued.

OSHA

Every OSHA regulatory action addressing significant occupational health and safety risks and their prioritization would be subject to the requirements of H.R. 9. (OSHA notes that Title III is captioned, "Risk Assessment and Cost/Benefit Analysis for New Regulations" and therefore does not appear to apply to non-regulatory agency activity such as enforcement or consultation. If Title III were applicable to enforcement or consultation activity, its requirements might apply to hundreds of additional documents such as inspection reports, abatement agreements, consultation reports, and compliance directives that may be interpreted to be risk assessments or risk characterizations under H.R. 9.)

For the remaining questions, the Department's responses will be presented under the three areas affected by Title III: OSHA, MSHA, and ESA's child labor hazardous occupations, respectively.

2. Using the definitions of "risk assessment" and "risk characterizations" set out in section 3107 of the Act, how many risk assessments and risk characterizations were prepared by, or on behalf of, the programs in the Department over the last fiscal year? Of those, how many would be considered to be a "screening analysis" exempted under Section 3103(b)(2)?

OSHA

Under the bill's definitions of "risk assessment" and "risk characterization," as set out in section 3107, OSHA has prepared two risk assessments as part of major rulemakings within the last fiscal year.

OSHA is continuing to develop and has received public comments on the risk estimates for methylene chloride, glycol ethers, indoor air quality, butadiene, and scaffolds in shipyards. None of these risk assessments/risk characterizations would be considered "screening analyses" as that term is defined by the bill.

MSHA

MSHA does not prepare formal risk assessments or risk characterizations in the context of its rulemaking activities. However, MSHA does prepare regulatory impact analyses for its rules, which address the cost and benefits of each proposed or final regulation. During the last fiscal year, MSHA issued the

following regulations, all of which included a discussion of the risk(s) identified and an analysis of the costs involved.

December 1993	Metal/Nonmetal Explosives Final Rule	Summarized in preamble with separate document made available upon request
February 1994	Abrasive Blasting & Drill Dust Control Final Rule	Summarized in preamble, with separate document made available upon request
May 1994	Underground Ventilation Proposed Rule	Summarized in preamble, with separate document made available upon request
November 1994	Decertification Proposed Rule	Included in preamble
November 1994	Testing and Evaluation by Nationally Recognized Testing Laboratories (NTRLs) and Use of Equivalent Testing and Evaluation Requirements- Proposed Rule	Included in preamble
January 1995	Metal/Nonmetal Explosives Proposed Rule	Included in preamble

None of MSHA's risk analysis activities would fall under the screening analysis exemption of § 3013.

#### **ESA**

ESA did not perform any Child Labor Hazardous Occupation Determinations in the last fiscal year. Current Hazardous Occupation listings are outdated. ESA published an ANPRM in the

Federal Register on May 13, 1994, seeking public comments on needed changes and future rulemaking in this area.

3. Please describe the Department's present practices, including references to any published guidelines or procedures, relating to risk assessment, risk characterization, cost-benefit analysis, or peer review.

#### OSHA

We believe that risk analysis is a necessary and appropriate tool for linking sound policy decisions with sound science. OSHA follows established scientific principles and nationally recognized guidelines, such as those of the National Academy of Sciences, when conducting analyses of risk. In addition, OSHA already follows many of the steps outlined in H.R. 9 (e.g., evaluation of some comparative and some substitute risks, presentation of alternative analytic models and assumptions, and description of ranges of uncertainty.) OSHA currently targets and tailors these techniques to the specific circumstances and risks under consideration and is concerned because H.R. 9 would force a "one-size-fits-all" approach to risk assessment on OSHA rulemaking. OSHA's current flexibility is particularly important because the Agency regulates or is planning to regulate a wide variety of different risks, including such hazards as chemical carcinogens, fire and explosion risks, infectious diseases, reproductive toxins, and workplace violence.

#### OSHA

OSHA prepares a regulatory impact analysis (RIA) for virtually every proposed and final regulatory action. The RIA analyzes the costs, benefits, and other potential impacts associated with regulations. The RIA is prepared in accordance with and in fulfillment of the requirements and obligations contained in the OSH Act (including relevant court decisions interpreting the Act), the Regulatory Flexibility Act, and Executive Order 12866.

The RIA characterizes the population that will be affected by the regulation and provides a description of the hazard being addressed. Data on current practices are evaluated to determine the degree of existing compliance with regulatory requirements and to enable OSHA to project costs and benefits accurately. Analysis of the impacts of a regulation includes a description of all potential costs and benefits (whether or not they can be monetized or even quantified), feasibility determinations, and implications for distributive considerations, specific populations, particular industries or markets, and effects on employment, productivity, international trade, and the environment.

The RIAs developed by OSHA to accompany regulations are reviewed and commented on by many sources. Under Executive Order 12866, OMB reviews all major rules, and particularly reviews the RIAs, to determine their adequacy and accuracy in providing the information necessary to support the regulation. The analysis and its underlying data and assumptions are made available to the public and are reviewed by interested parties, in particular by individuals with expertise in relevant areas. OSHA frequently solicits peer review on its analyses from recognized experts and professionals. Thus, OSHA's analyses are based on substantial evidence accumulated in the record from all available sources and are responsive to comments received.

#### MSHA

MSHA does not have any published guidelines or procedures relating to its present practices of evaluating the costs and benefits of new regulations. Executive Order No. 12866 requires that MSHA conduct an assessment of the costs and benefits of its regulatory actions to determine that the benefits justify the costs. Similarly, the Regulatory Flexibility Act requires MSHA to consider the impact of a proposed rule on small entities.

Even though MSHA has never had a rule that exceeded the \$100,000,000 threshold of recent Executive Orders, MSHA has always conducted a preliminary analysis of costs to determine the economic impact of its regulatory actions. In part, this analysis is conducted to determine the impact of the rule on small businesses and assure that the rule will not have a significant impact on a substantial number of such small entities.

In performing these analyses, MSHA first develops an industry profile to determine the number and type of mining operations (for example, coal or metal/nonmetal, small or large) and how many miners would be affected by the regulatory action. For example, recent proposed changes in ventilation safety standards would affect only underground coal mines, including both large and small mines. The Agency relies upon its own employment data to determine the population at risk. Recently, the presence of contractors has become an important consideration in determining the potential effects of a rule.

Once the population at risk has been determined, MSHA analyzes its accident and injury information to estimate the benefits of a rule. Although agency's reporting requirements capture accidents and injuries fairly well, information on harmful health effects in mining is less readily available, at times requiring MSHA to extrapolate benefits from experiences in other industries. MSHA's benefits analysis most frequently presents a qualitative discussion of the potential health and safety benefits that may result from promulgation of a rule,

rather than a definitive quantification of the benefits. MSHA does not conduct formal risk assessments for determining benefits. Nor does MSHA perform a cost-benefit ratio analysis. However, MSHA does apply a general cost effectiveness analysis to its regulatory actions.

MSHA estimates costs by first determining which elements of the rule will result in additional costs to the mine operator. These cost determinations frequently include assumptions about voluntary compliance and cost differentials related to mine size or commodity. Cost estimates are often derived from determining purchase and installation costs for equipment and machinery. For example, if a provision requires a piece of equipment, such as a fire suppression system on mobile diesel equipment, then costs are determined for the purchase, installation and maintenance of the equipment. In addition, costs are also determined for any recurring requirements in the rule such as inspections, training, maintenance, examination, or testing programs.

#### MSHA

The procedures for performing Hazardous Occupation Determinations are contained in 29 C.F.R. 570 Subpart D.

4. If enacted into law would the Act affect the Department's present practices as described in question 3? If compliance with the Act would require additional resources in carrying out such practices, please estimate the additional resources (in terms of dollars and personnel) that would be required to carry out the provisions of the Act.

#### OSHA

Although OSHA is aware that H.R. 9 will impose substantial resource and personnel costs on the Agency, a detailed breakdown of specific impacts has not been finalized. However, if section 3105(2) is interpreted to require analyses of the likelihood of each exposure scenario for every separately identifiable population of workers, OSHA would have to conduct extensive employer surveys to obtain industry-specific employment turnover data. Thus, this section (Section 3105(2)) of the bill alone would add an average of \$1 million (the approximate cost of a 5,000-establishment multi-sector survey) to the cost of each rule and would add a minimum one year delay while OSHA analyzes and tabulates survey results. In OSHA's recent cadmium rulemaking, this requirement would have cost 17 cadmium-exposed workers to lose their lives and another 78 overexposed employees to develop progressive kidney disease.

The adverse impacts of the bill on worker health and safety would be compounded at many steps in the risk analysis process. For example, if Title III's requirement to characterize the risks of exposure to every chemical that could potentially be substituted for the chemical being regulated is interpreted to require a risk assessment for every significant substitute, OSHA would have been required to conduct a total of 81 additional risk assessments, at a cost of \$4 million in contract funds and 28 years of staff effort, just to issue the seven safety and health rules that were proposed by OSHA in the last few years. Meanwhile, during the time that OSHA was gridlocked in the endless risk assessment loop, an estimated 377 workers, whose lives could have been saved by these regulations, would needlessly have died. In addition, risk assessments of substitutes will be controversial. The manufacturers of the substitutes will contest them. While manufacturers of competing substances are contesting which chemical is most dangerous, proceedings will be delayed for years and hundreds of workers will die.

#### MSHA

Effect of H.R. 9 on MSHA's standard-setting process. If enacted into law, the Act would render the health and safety standard-setting process currently in use at MSHA virtually unworkable. Currently, MSHA has a very small regulations staff and relies heavily on its technical staff to develop the substance of regulations. To engage in "risk assessments" and "risk characterizations," as defined in the Act, would demand tremendous additional resources. MSHA would have no choice but to engage outside contractors to perform the scientific analyses demanded by the "risk assessment" provisions of the Act. The expense of such services can be only roughly projected, but would certainly cost the taxpayers millions of dollars each year.

The most problematic issue would be the requirements for developing risk assessments for all forthcoming MSHA health regulations. The requirements of Title III would seriously hinder, if not halt, a number of health rulemakings currently under development. For example, MSHA is currently developing a final air quality rule, which would update many outdated permissible exposure limits (PELs) for chemicals found at mines as well as hazardous materials burned as fuel in cement kilns. Currently, MSHA is enforcing 22 year-old PELs. Title III would appear to require exhaustive and essentially air-tight risk assessments to support every new PEL, a requirement that would be impossible for MSHA to satisfy within its current resource limitations.

In short, the rigid and formalized procedures for risk assessment in Title III would have the effect of significantly limiting or eliminating MSHA's ability to address identified health problems through the regulatory process.

ESA

If enacted, Title III would substantially increase the process of making Hazardous Occupation Determinations. ESA would need to obtain assistance from other DOL agencies, such as OSHA, or from outside sources, in developing the expertise necessary to conduct a risk assessment. Moreover, ESA estimates that it would need additional FTEs and approximately \$3 million annually for contracts.

5. How does the Department obtain the information it uses to prepare risk assessments, cost-benefit analyses, or risk characterizations? Does the Department rely in part upon the private sector in providing the information needed by the Department to conduct such assessments or analyses? If so, would the Act require the Department to obtain additional information from the private sector in order to comply with the Act's requirements?

OSHA

OSHA obtains the information it uses to prepare its risk assessments, cost analyses, or risk characterizations from a number and variety of sources. Much of the information is submitted by parties directly affected by the regulation, such as labor unions representing exposed workers, trade organizations and industry representatives. This includes information on potential safety hazards and health effects, as well as data on exposure levels, available industrial hygiene and safety control measures, and associated cost data.

The agency relies heavily on information published in the peer-reviewed literature as well as information developed by experts from academia, professional consulting firms, national consensus groups (e.g., ANSI, National Safety Council, and ACGIH) and other government agencies (e.g., NIOSH, CDC, EPA). OSHA also obtains information on exposure, costs and industrial hygiene and safety control technology through ongoing industrial hygiene and safety compliance oriented inspections and through invitational, non-compliance site visits to establishments in affected industries.

OSHA relies on private sector contractors with available expertise in a wide variety of specific areas to provide some of the basic research and information necessary to develop particular regulations. Information is obtained from published literature and other data sources, from experts, discussions with employees and employers, and through site visits. For some regulations, a survey is conducted to provide statistical data regarding various industries and regulatory provisions. The bill

will require additional data to be prepared by the private sector (i.e., the regulated industries), because the private sector is likely to be the only source able to supply the type of data necessary to meet the requirements of the bill (e.g., substitutes used, costs, exposure levels). The bill would also require a greater amount of information to be collected from the private sector in order to document the potential effects of regulations in greater detail. This will substantially increase mandatory government paperwork for the private sector.

#### MSHA

In the course of developing a rule, MSHA solicits information from the private sector, including manufacturers, labor unions, and mine operators, on costs relevant to the rule. Under Title III, this exercise would need to be greatly expanded. The agency also relies heavily on information published in the peer-reviewed literature as well as information developed by experts from academia, professional consulting firms, and national consensus groups. The agency also relies on information on exposure, costs, benefits, and control technology from its inspection and technical staff. The bill would require MSHA to obtain additional information from the private sector in order to comply with the Act's requirements.

#### ESA

While ESA has no experience in risk assessments, comments are invited from the affected public as a regular part of its notice and comment rulemaking.

6. Please identify the regulations expected to be proposed or promulgated in the next two years which would require a Regulatory Impact Analysis under Title VII, an analysis of risk reduction benefits and costs or a certification under Subtitle B of Section 3201, or a peer review under Section 3301. What additional procedures would the Department be required to follow to issue such regulations if the Act were enacted into law? Would the Act permit judicial review of agency actions beyond what is presently permitted under the Administrative Procedure Act? Please estimate the additional time and resources that would be necessary to complete the expected rulemaking following the required procedures. If the Department is subject to court-ordered or statutory deadlines for completion of any such regulations, can the Department comply with the Act and still meet such deadlines?

**OSHA**

Virtually every regulatory action expected to be proposed or promulgated in the next two years, as listed in the draft Regulatory Schedule, would require a regulatory impact analysis, an analysis of risk reduction benefits and costs, and formal peer review. Procedures included in the bill would require additional and more detailed risk assessments and regulatory impact analyses, such as evaluations of individual industry subsectors and identification of potential substitutes. The additional burdens imposed by the bill on OSHA may double or triple the amount of resources needed to promulgate regulations.

The numerous procedural steps and analytical factors that H.R. 9 would add to OSHA rulemaking would greatly increase the scope of judicial review and each standard's vulnerability to invalidation on grounds that are not necessarily reflective of the standard's essential efficacy or feasibility. H.R. 9 also repeals § 611 of the Regulatory Flexibility Act, which now precludes judicial review of an agency's compliance with that Act, and repeals § 3504(h)(9) of the Paperwork Reduction Act, which now precludes judicial review of OMB's decision to approve or not act upon a paperwork requirement in an agency rule. In addition, Title VIII creates a new private cause of action against agencies and agency employees based on claims that the agency or employee retaliated against a private person because the private person disclosed certain information.

**MSHA**

In its latest published agenda (October 1994), MSHA has scheduled the issuance of the following regulations in the next 2 years. All of these regulations would require a regulatory impact analysis under Title VII:

Decertification  
 Legal Identity  
 Independent Laboratory Testing  
 Metal/Nonmetal Explosives  
 Certification of  
     Workplace Examiners  
 Examination of Surface Areas of Underground Coal Mines  
 Conveyor Belt Approval  
 Metal/Nonmetal Impoundments  
 Diesel-Powered Equipment  
 Hazard Communication  
 Air Quality  
 Carbon Monoxide Monitors  
 Respirator Approval  
 Firefighting/Escape/Evacuation  
 Waterlines in Belt Conveyor Entries

Metal/Nonmetal Gassy  
 Mines  
 Single Shift Sampling  
 Training (construction policy)  
 Training (inclusive)  
 Respirable Coal Mine Dust  
 Diesel Particulate  
 Longwalls (including high voltage)  
 Ventilation  
 Confined Spaces  
 Belt Entry Ventilation  
 Bloodborne Pathogens

### ESA

Essentially, Title VII would impact all Employment Standards Administration (ESA) planned rulemaking actions, because the definition of a major rule would include those rules affecting 100 individuals. In addition to the current procedures for notice and comment rulemaking, ESA would have to conduct a risk assessment for its child labor hazardous occupation determinations. Following is a list of affected regulations, which is based generally on ESA's October 1994 regulatory agenda.

Government Contractors Nondiscrimination and Affirmative Action Obligations, 41 CFR Part 60-1. Notice of Proposed Rule Making (NPRM).

Child Labor Hazardous Occupation Orders, 29 CFR Part 570. NPRM.

FLSA Executive, Administrative and Professional Employees, 29 CFR Part 541. NPRM.

Wage Payments under the FLSA, 29 CFR Part 531. NPRM.

Affirmative Action and Nondiscrimination Obligations of Contractors and Subcontractors for Disabled Veterans and Veterans of the Vietnam Era, 41 CFR Part 60-250. NPRM.

Labor Standards for Federal Service Contracts. NPRM.

FLSA Domestic, 29 CFR Part 552. NPRM.

Procedure for Handling Discrimination Complaints under Federal "Whistleblower" Protection Statutes, 29 CFR Part 24. NPRM.

Standards for Waivers under Section 503 of the Rehabilitation Act, 41 CFR Part 60-741, NPRM.

Proposed regulations regarding the right of first refusal on Federal service contracts. NPRM.

Child Labor Regulations, Orders, and Statements of Interpretation (Sports Attendants), 29 CFR Part 570. NPRM.

Several sections of the regulations implementing the Longshore and Harbor Workers Compensation Act will be revised to streamline administration and to clarify standards for resolving disputes over medical fees. NPRM.

Migrant and Seasonal Agricultural Worker Protection, 29 CFR Part 500. NPRM.

Procedures for Predetermination of Wage Rates and Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction (use of helpers). NPRM.

CWHSSA, SCA, DBA, 29 CFR Parts 4 & 5. Regulatory action necessitated by amendments to the subject laws contained in the Federal Acquisition Streamlining Act of 1994, signed by the President 10/13/94. NPRM.

7. Are the requirements of section 3105 for risk characterization (taking into account the definitions in 3106) consistent with the Department's understanding of sound scientific principles for risk assessment and risk characterization? Would the requirements of section 3105 preclude the Department from considering any information, models, or assumptions in assessing or characterizing risk? How would the Department be able to take into account risks to special subpopulations which may have higher susceptibility than "average"?

#### OSHA

In general, Section 3105's requirements for risk characterization, defined by the bill as "that element of a risk assessment that involves presentation of the degree of risk in any regulatory proposal, or decision," are consistent not only with OSHA's understanding of sound scientific principles but with the way the agency practices risk communication in its Federal Register notices, publications and reports to the public. For example, OSHA carefully describes the working populations that are subject to the hazard being regulated by discussing the processes, occupations, industries and demographic characteristics of the exposed workforce. In addition, OSHA provides the public with information on other similar risks (and, in particular, with information on other occupational risks).

The risks posed by the major chemical substitutes for a regulated chemical are also qualitatively evaluated where data on these substitutes is available. Finally, OSHA routinely dis-

cusses and describes all risk assessment comments received from peer reviewers and rulemaking participants. OSHA also carefully reviews and analyzes all risk assessments submitted by members of the public and scientific community, and these reviews frequently extend to analyses and reanalyses of the underlying toxicologic and epidemiologic data. For OSHA's 1987 formaldehyde standard, for example, the preamble to the final rule devoted 64 pages of the Federal Register to a full and open discussion of the health effects and risk assessment approaches suggested and submitted by participants in the rulemaking. Section 3105's risk characterization requirements would not appear to preclude consideration of any model, inference or assumption used in connection with a risk assessment or with the dissemination of information about such an assessment.

#### MSHA

Since MSHA does not conduct formal risk assessment for its rulemakings, MSHA has no current in-house expertise to evaluate whether the requirements of section 3105 represent sound scientific principles for risk assessment.

#### ESA

ESA has no basis to evaluate whether the requirements of section 3105 represent sound scientific principles for risk assessment.

8. To the extent not already addressed in previous answers, please identify all risk assessment documents, regulatory proposal of decisions, reports to Congress, or other documents made available to the public by the Department which include characterizations of risks that would be subject to the requirements of section 3105.

#### OSHA

See OSHA answer to question 1.

#### MSHA

MSHA only develops characterizations of risk in the context of its rulemaking activities. However, MSHA does publish guidelines, health hazard alerts, fact sheets, and other related materials, that contain descriptions of risks.

#### ESA

Not Applicable.

9. Please estimate the cost of complying with the peer review requirements of section 3301, taking into account the provisions of Title VII requiring Regulatory Impact Analyses. How would the Department implement the requirement for peer review of "economic assessments" "economic information," and "cost assessments"? Would the Department be precluded from issuing any regulation until the required peer review, peer review report, and response to the peer review, has been completed and made available to the public? How long would such a process be likely to take? Would such peer review panels be subject to the Federal Advisory Committee Act?

#### OSHA

At present, OSHA often seeks peer review of its economic and scientific assessments, and all documents pertaining to its regulatory impact analyses are placed into the rulemaking docket, where they are accessible to the public. OSHA also evaluates all comments received on these documents, analyzes any economic data submitted by interested parties, and responds to all substantive comments received in its final regulatory impact assessments. However, it is current OSHA practice to seek peer review only where an economic assessment raises difficult or novel economic or methodological questions. OSHA conducts public hearings which always provide the opportunity for peer review even if no other formal review process is undertaken. Being required to implement the bill's formalized peer review procedures in every case would be both inefficient and wasteful of public funds.

OSHA estimates that complying with the peer review provisions of the bill would require a minimum of an additional 12 to 15 months for each regulatory action subject to these requirements. This would allow time for the agency to convene the peer review panel, and have the panel conduct its review and draft its report to the agency. Subtitle C of Title III is written in mandatory terms. If OSHA issued a rule without fully complying with the peer review requirements, the rule could be overturned by a reviewing court. The peer review panels would probably be advisory committees within the meaning of Section 3 of the Federal Advisory Committee Act (FACA) and would therefore have to be chartered. As part of Administration's reinvention efforts, the number of Federal Advisory Committees has been sharply reduced and it is not clear how this bill would interact with those initiatives.

#### MSHA and ESHA

Generally, see OSHA's response, above.



## U. S. Department of Justice

## Office of Legislative Affairs

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Office of the Assistant Attorney General

Washington, D.C. 20530

February 3, 1995

Honorable George E. Brown, Jr.  
Ranking Democratic Member  
Committee on Science  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Representative Brown:

This is in response to your letter to the Attorney General regarding Title III of H.R. 9, the Risk Assessment and Communication Act of 1995. The Department supports the appropriate use of risk assessment and cost benefit analysis in the promulgation of regulations. However, we have serious concerns with Title III.

Below are responses to your specific questions about Title III's potential impact on the Department's programs.

1. Please identify the programs in the Department which would be subject to the requirements of the Risk Assessment and Communication Act of 1995 (Title III of H.R. 9), taking into account Title VII and other relevant sections of H.R. 9.

The precise scope of Title III of H.R. 9 is unclear, because key terms such as "major rule," "risk assessment," "risk characterization" and "screening analysis" are not clearly defined. It could be argued that some Bureau of Prisons (BOP) regulations constitute "regulatory programs designed to protect human health, safety, or the environment" (§ 3103(b)(1)) and that therefore the provisions of subtitle A of Title III would be applicable to BOP regulations such as 28 CFR 551, subpart N (regulations on inmate smoking); 28 CFR 551, subpart A (inmate grooming); 28 CFR 549, subpart A (inmate HIV and infectious diseases). Similarly, it could be argued that pending Immigration and Naturalization Service (INS) regulations regarding waiver procedures for exclusion of aliens with "contagious diseases of public health significance" or certain physical or mental disorders or behavior under 8 U.S.C. § 212(a)(1) would be subject to subtitle A of Title III. Indeed, it could even be argued that some Department of Justice litigation pleadings and briefs in cases involving federal regulatory programs designed to protect human health, safety, or the

environment fall within the scope of subtitle A of Title III. It appears, however, that the Department's regulations would not fall within the definition of a major rule under Title III, and therefore would not be subject to subtitles B and C of Title III.

2. Using the definitions of "risk assessment" and "risk characterizations" set out in section 3107 of the Act, how many risk assessments and risk characterizations were prepared by, or on behalf of, the programs in the Department over the last fiscal year? Of those, how many would be considered to be a "screening analysis" exempted under Section 3103(b)(2)?

The following rules published by the Department in 1994 arguably meet the definition of "regulatory programs designed to protect human health, safety, and the environment," and arguably involved the characterization or assessment of risk. They would not be considered a "screening analysis" exempted under Section 3103(b)(2). Accordingly, the Department would have been required to comply with the procedures and requirements of subtitle A of Title III in the promulgation of these regulations:

- The Justice Management Division (JMD) Department-wide no-smoking rule for Department of Justice workplaces
- BOP's rule restricting smoking by inmates and staff
- BOP's rule on treatment of inmates on hunger strikes
- BOP's rule on compassionate release of terminally ill inmates
- BOP's rule on arrest authority for BOP personnel in the searching of non-inmates for contraband and prohibited objects (e.g., weapons, drugs, sharp objects)
- BOP's rule on the use of force and application of restraints
- BOP's rule requiring participation of certain inmates in drug abuse and treatment programs

3. Please describe the Department's present practices, including references to any published guidelines or procedures, relating to risk assessment, risk characterization, cost-benefit analysis, or peer review.

Because of the nature of the rules adopted by the Department, we have not been required to engage in risk

assessment, risk characterization, cost-benefit analysis, or peer review. To the best of our knowledge, the Department does not have any practices, procedures or guidelines relating to such matters. The Department prepared "regulatory impact analyses" under Executive Order 12291 for the INS employer sanctions rule in 1987 and the Americans with Disabilities Act in 1991. Neither of those programs falls within the Title III definition of a "regulatory program designed to protect human health, safety, or the environment".

4. If enacted into law, how would the Act affect the Department's present practices as described in question 3? If compliance with the Act would require additional resources in carrying out such practices, please estimate the additional resources (in terms of dollars and personnel) that would be required to carry out the provisions of the Act.

If Title III were enacted, and if regulations such as those promulgated by JMD, BOP and the INS were deemed to be subject to the Title, then the Department would require additional resources to satisfy the Title's requirements. We are unable to provide cost or personnel estimates at this time. -

5. How does the Department obtain the information it uses to prepare risk assessments, cost-benefit analyses, or risk characterizations? Does the Department rely in part upon the private sector in providing the information needed by the Department to conduct such assessments or analyses? If so, would the Act require the Department to obtain additional information from the private sector in order to comply with the Act's requirements?

As explained above, the Department historically has not prepared formal risk assessments, cost-benefit analyses, or risk characterizations. If the Department were required to prepare them, the information would probably be collected by the Department (or its contractors) rather than from the private sector.

6. Please identify regulations expected to be proposed or promulgated in the next two years which would require a Regulatory Impact Analysis under Title VII, an analysis or risk reduction benefits and costs or a certification under Subtitle B of Section 3201, or a peer review under Section 3301. What additional procedures would the Department be required to follow to issue such regulations if the Act were enacted into law? Would the Act permit judicial review of agency actions beyond what is presently permitted under the Administrative Procedure Act? Please estimate the additional time and resources that would be necessary to complete the expected rulemaking following the required procedures. If the Department is subject to court-ordered or statutory deadlines for completion of any such

regulations, can the Department comply with the Act and still meet such deadlines?

We estimate that over 100 of the rules that the Department has pending or is planning to adopt would affect more than 100 persons, and so would require a complete regulatory analysis under Title VII. The definition of a "major rule" in § 7004(b) of Title VII (affecting 100 persons or imposing compliance costs of \$1 million on any person) would mean that the vast majority of Department of Justice rules would fall within the scope of "major rules" even if their impact is really very minor. The 100-person trigger for "major rule" status would seem to apply to practically every federal rule and require agencies to prepare a full regulatory impact analysis for even the most innocuous rules.

Since the adoption of Executive Order 12866 on Sept. 30, 1993, the Department has identified approximately 20 rules as "significant regulatory actions" (which means that OMB must review the rule prior to publication under the Executive Order's procedures) and most of them are still pending development. None of the Department's rules have been deemed to be "economically significant" (akin to the "major rule" standard of Executive Order 12291) because of their impact on the economy, jobs, the environment, etc., which would require a more detailed analysis of their provisions under the standards of Executive Order 12866. Approximately 140 regulatory matters that have been published since 1993 or are now pending on the Department's regulatory status report have been determined not to be "significant" and do not need to be submitted to OMB for review, much less be the subject of a regulatory analysis. For such rules, the Department provides a summary description of the rule and its impact to OMB prior to publication.

Under Title VII of H.R. 9, the great majority of those 140 rules would appear to be "major rules" because they affect more than 100 persons. Thus, the Department would have to prepare a full regulatory impact analysis for each one before it could be published.

- Under Title VII, virtually every rule of BOP on matters such as work details, transfers, educational programs or other purely routine matters of prisoner management would be deemed a "major rule" because they affect more than 100 prisoners. BOP has pending rules relating to inmate grievance procedures, volunteer community service projects, English-as-a-second-language programs, administrative remedy procedures, post-secondary education programs, plastic surgery policies,

inmate work and performance pay, and drug abuse treatment programs.

- Virtually every immigration or naturalization regulation would also be covered -- even such matters as clarifying the procedure for filing applications. INS has a large number of pending "non-significant" rules relating to matters such as procedures for administrative naturalization, standardized testing for naturalization, classification of NATO dependents, procedures governing Transit Without Visa nonimmigrants, requirements for applicants for family unity benefits, requirements for application for nonresident alien border crossing cards, requirements relating to marriages by aliens during the pendency of deportation or exclusion proceedings, restriction of the abuse of the B-1 business visitor visa, requirements for the Visa Waiver Pilot Program, rules governing employment of students, evidence required for immigrant visa petitions, admission of nurses, and requirements for applications for suspension of deportation.
- The FBI would have to conduct a complete regulatory analysis for its rule to raise by \$1 the cost of obtaining criminal history records to keep up with increased costs.

Title III of H.R. 9 uses a different definition of "major rule" which does not include the 100-person standard included in Title VII. The Department does not expect to promulgate any rules that would meet the definition of major rule under Title III and the Department's rules would therefore not be subject to the requirements of subtitles B or C of Title III.

Title III would permit judicial review beyond what is presently permitted under the Administrative Procedure Act. As explained in our previous letter on Title III, this is a serious concern because it will create delays and litigation and make our client federal agencies less efficient and less responsive to the regulated community.

We would expect the requirements of Title VII to add to the time necessary to complete BOP, INS, and other rulemaking procedures, but we are unable to provide a time estimate at this time.

7. Are the requirements of section 3105 for risk characterization (taking into account the definitions in 3106) consistent with the Department's understanding of sound scientific principles for risk assessment and risk

characterization? Would the requirements of section 3105 preclude the Department from considering any information, models, or assumptions in assessing or characterizing risk? How would the Department be able to take into account risks to special subpopulations which may have higher susceptibility than "average"?

We understand that there are significant problems with the requirements of section 3105. We defer to the explanations of the Environmental Protection Agency and other agencies with particular expertise in this area.

8. To the extent not already addressed in previous answers, please identify all risk assessment documents, regulatory proposals or decisions, reports to Congress, or other documents made available to the public by the Department which include characterizations of risks that would be subject to the requirements of section 3105.

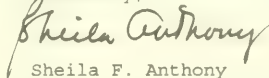
See answers to questions 1 and 2 above.

9. Please estimate the cost of complying with the peer review requirements of section 3301, taking into account the provisions of Title VII requiring Regulatory Impact Analyses. How would the Department implement the requirement for peer review of "economic" assessments, "economic information," and "cost assessments"? Would the Department be precluded from issuing any regulation until the required peer review, peer review report, and response to the peer review, had been completed and made available to the public? How long would such a process be likely to take. Would such peer review panels be subject to the Federal Advisory Committee Act?

Because the Department's regulatory activities would not constitute major rules under Title III, the Department would not be subject to that Title's peer review requirements. The peer review program required by Subtitle C of Title III appears to require the peer review panels to provide consensus advice to federal agencies, as opposed to permitting peer reviewers to provide their individual views. If so, then the Federal Advisory Committee Act would apply to the peer review panels.

The Office of Management and Budget has advised this Department that there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,



Sheila F. Anthony  
Assistant Attorney General

cc: Robert S. Walker  
Chairman  
Committee on Science

**The Secretary of Energy**

Washington, DC 20585

February 6, 1995

The Honorable George E. Brown, Jr.  
Ranking Minority  
Committee on Technology and Competitiveness  
U. S. House of Representatives  
Washington, D.C. 20515

Dear Congressman Brown:

In response to your request of January 20, 1995, enclosed are the Department of Energy's views on Title III of the proposed Risk Assessment and Communication Act of 1995. The Department has concerns with the risk assessment provisions of H.R. 9 for the following reasons.

The Department of Energy is very supportive of risk-based approaches to decisions and actions designed to protect the environment, worker and public health, and safety. Senior Department of Energy officials participate in the Clinton Administration's Regulatory Working Group is crafting a rational and coherent framework to guide environment, safety and health regulation. Department of Energy was the first Federal agency to officially adopt the Risk Principles endorsed by the Working Group enclosed. These principles establish a scientifically sound and practicable guide to risk assessment procedures and should help ensure that risk assessments conducted by the Department are consistent, transparent and defensible.

As you know, the Department of Energy is managing the biggest environmental cleanup in the nation's history. We are committed to carrying out this cleanup so that risks to our workers, the public, and the environment are addressed responsibly and efficiently. We recognize the mandates associated with environmental laws such as the Resource Conservation and Recovery Act and Superfund, and understand the difficulties of reliably predicting the costs or benefits of a particular cleanup project or area of contamination. We are committed to acting in accord with the law and in a consultative and collegial manner with our regulators and stakeholders.

While it is our view the major programs and activities at the Department of Energy would come under the provisions of H.R. 9, the scope of this legislation needs to be clarified in order to predict exactly how the Department's functions would be affected. The application of Title III to the Department of Energy is complex in that the Department of Energy has both regulatory authority in certain programs and is a regulated entity in others.

Our first major concern is that the broad language of the bill will likely envelop a wide range of Departmental activities designed to assess risk and would slow and complicate our programs to protect our workers and the public. Among these are activities such as safety inspections of nuclear weapons facilities, analyses of risks associated with operations such as plutonium stabilization, and the promulgation of safety, health and environmental orders and nuclear safety rules. Federal regulatory initiatives that address environment, safety and health risks associated with gas, oil and coal activities within the Department of Energy and in the private sector would require a significant additional level of analysis and support to comply with the bill's requirements.

Secondly, the prescriptive approach to risk analysis described in the bill will be imposed on a range of risk appraisal activities that are not necessarily efficiently or effectively addressed by the one-size-fits-all approach of the bill. It will impose significant analytical burdens on the Department, appreciably increase the cost of all such assessments, and delay completion of most analyses and implementation of proposed rules

Third, the lack of any defined way to reach closure on the adequacy of the risk assessment or peer review processes, and the potential for judicial review of these processes, will likely result in disputes being referred to the courts for settlement. This is especially probable in instances where there are sharp technical and policy disagreements about the desirability of one or another course of action, such as the opening of the Waste Isolation Pilot Plant or the suitability of the Yucca Mountain Waste Repository for radioactive waste disposal.

Finally, the legislation implies assumptions of certainty and levels of scientific understanding applicable to assessing human health and environmental risk that simply do not exist. The implied precision in the prescribed risk assessment processes is not scientifically supportable and the result will undoubtedly be massive uncertainty and continuous litigation

We hope this information is helpful to you and other members of the Committee. If you have any questions or need further information, please contact me or have your staff contact William J. Taylor, III, Assistant Secretary for Congressional and Intergovernmental Affairs, at 202-586-5450.

The Office of Management and Budget has advised that there is no objection, from the standpoint of the Administration's program, to the submission of this report to the Committee.

Sincerely,

A handwritten signature in cursive script, reading "Hazel R. O'Leary". The signature is written in dark ink and is positioned above the printed name.

Hazel R. O'Leary

Enclosure  
Questions and Answers

**ANSWERS TO QUESTIONS FROM CONGRESSMAN BROWN ON  
TITLE III OF H.R.9**

2/3/95

***Q.1 Please identify the programs in the Department which would be subject to the requirements of the Risk Assessment and Communication Act of 1995 (Title III of H.R. 9), taking into account Title VII and other relevant sections of H.R. 9.***

**Answer:**

- o Due to the broad language of the bill, particularly the very sweeping definition of risk assessment, major programs and projects carried out by the Department of Energy would come under the provisions of H.R. 9.
- o H.R. 9 could have implications for elements of the Department concerned with environmental restoration and with protecting environment, safety and health. Among these are activities such as safety inspections of nuclear weapons facilities; analyses of risks associated with operations such as plutonium stabilization; and the promulgation of safety, health and environmental orders and nuclear safety rules designed to protect ecosystems, workers and the public.
- o Federal regulatory initiatives that address environment, safety and health risks associated with gas, oil and coal activities within DOE and in the private sector would require a significant additional level of analysis and support to comply with the bill's requirements.

***Q.2.a. Using the definitions of "risk assessment" and "risk characterization" set out in section 3107 of the Act, how many risk assessments and risk characterizations were prepared by, or on behalf of, the programs in the Department over the last fiscal year?***

**Answer:**

- o Given the broad definition of risk assessment under H.R. 9, most environment, safety and health activities involving appraisal of risks would potentially fall under the requirements of H.R. 9. These involve vulnerability assessments, oversight inspections, accident investigations, safety analysis reports, and operational readiness reviews.
- o Environmental assessments and environmental impact statements prepared under National Environmental Policy Act contain information that would meet the definitions of risks assessment in H.R. 9. In the last fiscal year, DOE issued 31 environmental assessments and 8 environmental impact statements.
- o The Office of Environmental Management alone has completed 90 risk assessments at Department sites in the last two years. These assessments are

part of the initial stages of efforts to address some 3700 contaminated sites in 34 States. These efforts are done in compliance with external regulations (i.e., EPA's), and thus would be affected by any changes that H.R. 9 imposes on EPA rules.

***Q.2.b. Of those, how many would be considered to be a "screening analysis" exempted under Section 3103 (b)(2)?***

Answer:

- o It is not clear what constitutes "screening analysis" given the existing language H.R. 9. The Department believes that the preliminary assessments under RCRA and CERCLA might be considered "screening analyses." However, since the majority of these are done in compliance with external regulations, their status for purposes of H.R.9 would likely be determined by external regulatory authorities such as EPA.
- o One major Department site, the Idaho National Engineering Laboratory has closed out 115 "potential release sites" as "no action sites" through "screening level" risk assessments (possibly similar to the "screening analysis" contemplated in section 3103(b)(2) of the bill). The duration of these assessments can range from a few months to a year and cost in the hundreds of thousands of dollars.

***Q.3. Please describe the Department's present practices, including references to any published guidelines or procedures, related to risk assessment, risk characterization, cost-benefit analysis, or peer review.***

Answer:

- o In general most of DOE's current risk assessments and characterization do not accommodate themselves to the "one-size fits all" approach set forth in subsection (b) of Sec. 3104, the risk characterization and communication principles of Sec. 3105, risk reduction benefits and cost principles of Sec. 3201, or the peer review program in Sec. 3301.

Title III contains highly subjective directives and qualifiers such as "to the maximum extent feasible", "inclusive of all relevant data", "explain the basis for any choices". Moreover, the inherent large uncertainties and paucity of data in risk assessments and cost-benefit analyses, the highly subjective nature of the approach and the required elements of the process (risk characterization and peer review) mandated by H.R.9 will likely give rise to debates and disputes between various stakeholders. The proposed bill contains no provisions for resolving such disputes, which are likely to be settled in court.

**Q.4.** *If enacted into law, how would the Act affect the Department's present practices as described in question 3? If compliance with the Act would require additional resources in carrying out such practices, please estimate the additional resources (in terms of dollars and personnel) that would be required to carry out the provisions of the Act.*

Answer:

- o The broad language in H.R. 9 will likely envelop a wide range of Departmental activities designed to assess risk. Among these are safety inspections of nuclear weapons facilities, analyses of risk associated with plutonium stabilization, environmental impact analyses and the promulgation of occupational safety, health, environmental, and nuclear safety orders and rules designed to protect workers and the public from hazards.
- o Indirect impacts on DOE programs would occur as a result of changes in external regulations. These would include compliance activities/programs such as baseline risk assessments, preliminary risk assessments, limited field investigations, and feasibility studies under the Comprehensive Environmental Liability and Compensation (CERCLA); performance assessments, preliminary assessments, RCRA facility investigations, and corrective measures studies under the Resource Conservation and Recovery Act (RCRA). The bill's full impact on these activities is difficult to predict.
- o For any major rules proposed by DOE, the requirement to perform a risk assessment, cost benefit analysis, peer review and regulatory impact analysis would entail consideration of highly uncertain parameters at every stage of the process. These would all be subject to debate and challenge, which will invariably lead to delays in developing major rules.

**Q.5.** *How does the Department obtain the information it uses to prepare risk assessments, cost benefit analyses, or risk characterizations? Does the Department rely in part upon the private sector in providing the information needed by the Department to conduct such assessment or analyses? If so, would the Act require the Department to obtain additional information from the private sector in order to comply with the Act's requirements?*

Answer:

- o Data and information are obtained through DOE sources and its contractors as well as through public participation in program- or project-specific activities.
- o The Act would require new, costly, time consuming layers of analysis for even critically important health and safety regulations. The prescriptive language of the Act and the uncertainty in its applicability to Departmental and private

sector activities indicate that the requirements for additional data for risk assessments, cost/benefit analyses and risk characterizations are greatly increased, which in turn will increase costs to the Department and the taxpayers.

***Q.6.a. Please identify the regulations expected to be proposed or promulgated which would require a Regulatory Impact Analysis under Title VII, an analysis of risk reduction benefits and costs or a certification under Subtitle B of Section 3201, or peer review under Section 3301.***

Answer:

- o Most of the Department's rulemakings, with the possible exception to some "housekeeping" rulemakings, are likely to be subject to one or more of the various provisions of H.R. 9. This is due in part to the low threshold used to define a "major rule" under Title VII -- Regulatory Impact Analysis.

***Q.6.b. What additional procedures would the Department be required to follow to issue such regulations if the Act were enacted into law?***

Answer:

- o Most of the affected rules are already subject to numerous regulatory impact analysis requirement such as those imposed by Executive Order 12866, NEPA, the Paperwork Reduction Act, and regulatory flexibility analysis. In addition, the Department requires for each new rulemaking the preparation of a Rulemaking Development Plan which includes an evaluation of the need for regulations and a cost/benefit analysis, as appropriate. In the areas of risk benefit/cost analysis and peer review, the bill would expand existing statutory requirements and impose significant new requirements.

***Q.6.c. Would the Act permit judicial review of agency actions beyond what is presently permitted under the Administrative Procedure Act?***

Answer:

- o While H.R. 9 would not formally amend the APA's judicial review provisions, section 6001 of H.R. 9 would eliminate the current restriction on judicial review of agency actions taken or not taken with respect to regulatory flexibility analyses (5 U.S.C. 611). Requiring a risk assessment or risk benefit/cost analysis could be challenged. Moreover, it would ask courts to resolve questions involving substantial scientific uncertainty that they may not be well-equipped to resolve.

***Q.6.d Please estimate the additional time and resources that would be necessary to complete the expected rulemaking following the required procedures.***

Answer:

- o The required procedures under H.R. 9, specifically the required peer review process, could increase significantly the time and expense required to complete the more complex rules. However, it is not possible to estimate the full effect at this time.
- o DOE relies heavily on internal expertise in some areas of nuclear safety and nuclear weapons safety. For example, most existing knowledge on plutonium resides within the DOE community; external peer review of environment, safety and health issues relating to plutonium would probably not be achievable without use of "internal" experts.

***Q.6.e If the Department is subject to court-ordered or statutory deadlines for completion of any such regulations, can the Department comply with the Act and still meet such deadlines?***

Answer:

- o The potential universe of Department rules affected by H.R. 9 includes the most complex rules which the Department has in progress.
- o Completion of these rules within applicable statutory deadlines is problematic even in the absence of the additional requirements of H.R. 9. Imposition of new and more onerous requirements will make such completion even more difficult.

***Q.7.a Are the requirements of section 3105 for risk characterization (taking into account the definitions in 3106) consistent with the Department's understanding of sound scientific principles for risk assessment and risk characterization?***

Answer:

- o The text implies achievable levels of certainty and scientific understanding that do not exist for assessing human health and environmental risks associated with substances in the environment. There is no acknowledgment in the bill of the different types of risk analyses that would be covered by this legislation.
- o The bill also implies precision in the cost/benefit process that is not supported by data or experience.
- o Some of the factors that should be considered in decision-making (such as distribution and magnitude of risks and benefits, choices among alternative

approaches to reducing risk, prevention of releases and/or exposures, environmental justice, individual preferences, quality of life, intergenerational transfers, effectiveness of management decisions) are not acknowledged, nor is the judgment that is required for such decisions, given the uncertainties that exist for both risk and cost-benefit analyses.

- o The concept of a two-way, open dialogue and exchange of information for risk communication is discussed in the findings (Sec. 3001) but is not mentioned in the rest of the bill (e.g., in Sec. 3105). The National Academy of Sciences and DOE believe that such dialogue is essential to public acceptance of risk assessment as a decision tool.
- o In Sec. 3104 and Sec. 3105, it is not acknowledged that there is currently no standard methodology for comparing different types of risk and that there are many approaches to doing so.

**Q.7.b. *Would the requirements of section 3105 preclude the Department from considering any information, models, or assumptions in assessing or characterizing risk?***

**Answer:**

- o While the requirements do not appear to preclude the Department from considering any information in assessing or characterizing risk, they imply a prescriptive "cancer-based" risk assessment methodology that may preclude the use of more qualitative public health based approaches to evaluating safety and health risks.
- o In Sections 3105, 3107, 3201, and 3301, concepts of policy, science, economics, and cost-benefit analyses are mixed, without transparency or awareness that these functions are the responsibility of, and are performed by, different individuals, offices, and agencies.

**Q.7.c. *How would the Department be able to take into account risks to special subpopulations which may have higher susceptibility than "average"?***

**Answer:**

- o While this issue is of great concern to the Department and the regulators, this bill does not explicitly address it. We oppose risk methodologies that would minimize or diminish concerns related to our children, to pregnant women, the elderly, and others who are often disproportionately affected by environmental, health and safety threats.

**Q.8. *To the extent not already addressed in previous answers, please identify all risk assessment documents, regulatory proposals or decision, reports to Congress, or other documents made available to the public by the Department which include characterizations of risks that would be subject to the requirements of section 3105.***

A.8. Already addressed in previous answers.

Q.9. *Please estimate the cost of complying with the peer review requirements of section 3301, taking into account the provisions of Title VII requiring Regulatory Impact Analysis. How would the Department implement the requirement for peer review of "economic assessments", "economic information", and "cost assessments"? Would the Department be precluded from issuing any regulation until the required peer review, peer review report, and response to the peer review, had been completed and made available to the public? How long would such a process be likely to take? Would such peer review panels be subject to the Federal Advisory Committee Act?*

Answer:

- o DOE relies heavily on internal expertise in the areas of nuclear safety and nuclear weapons safety. For example, most existing knowledge of plutonium resides within DOE or its contractors. External peer review of environment, safety and health issues relating to plutonium would be a costly burden on the Department without any added value.
- o Since the public consultation and peer review program involve the solicitation of advice by a Federal agency from non-Federal employees, it would probably implicate the Federal Advisory Committee Act (FACA), which would entail further delays.



**The Under Secretary of Energy**  
Washington, DC 20585

MEMORANDUM FOR: ALL DOE ELEMENTS

FROM: Charles B. Curtis, Under Secretary

SUBJECT: Principles for Using Risk Analysis

*Charles B. Curtis*

A very public discussion on risk assessments and analyses has been prominent in the press recently, yet this discussion itself is not new. Policy makers, scientists, economists, and students of public administration have long debated the subject. The growing body of literature that has been generated is now receiving increased visibility, capturing the attention of both the Congress and many stakeholders throughout the Department of Energy's far flung community. A general framework for risk analysis is a timely and appropriate aid to policy making.

A major departmental effort in this regard was the request made last year to the National Academy of Sciences to advise the Department on whether and how risk and risk-based decisions could be incorporated into the Environmental Management Program. This resulted in the January 1994 report, *Building Consensus through Risk Assessment and Management of the Department of Energy's Environmental Remediation Program*. Copies of this report were distributed earlier this year, and we are in the process of addressing and implementing the recommendations made in it. Among other findings, the report determined that risk-based decision making was both feasible and desirable.

The report's recommendations track well with our own departmental Strategic Plan which specifies, in part, that the principal quality objective -- and greatest challenge -- is "to eliminate the risks and imminent threats posed by past departmental activities and decisions." Similarly, the primary mission of the Environmental Management Program is protecting human health and the environment, the first goal of which must be, and is, to address urgent risks and threats. Another is to provide for a safe workplace. Without credible risk assessment and good risk management, our central environmental goals cannot be met.

Because of this increased emphasis on risk activities, the Department needs to give focus to and guidance for all such activities now being conducted or anticipated. Initial guidance is attached for your information and appropriate action.

The attached risk principles are based on principles developed for Federal agencies over the past several months by an interagency committee, led by the White House Office of Science and Technology Policy. The interagency committee principles were modified to apply more specifically to Department of Energy programs and processes, to accommodate stakeholder values, to more specifically address inter-generational issues, and to clarify the role of prevention programs and social and economic considerations in risk management. They are designed to be a first cut at defining risk analysis, its purposes, and the principles to be followed if it is to be done well and credibly. They include general principles; principles for risk assessment, management, and communication; and principles for priority setting using risk analysis.

These principles are aspirational rather than prescriptive. Their application requires flexibility and practical judgment. The science of risk analysis is rapidly changing and its use is a function of several factors -- including legal mandates and available resources -- that vary from one regulatory program to another. These principles are therefore not offered as conclusive, complete, or irrevocable; they are intended to be used as a point of departure for our further efforts. It is important to emphasize that these principles are intended to be read and applied as a whole.

Furthermore, these principles are necessarily interim. Comments are invited regarding these principles and their use, and should be directed to Dr. Carol J. Henry or Mark A. Gilbertson at (202) 586-7150 in the Office of Environmental Management, Office of Integrated Risk Management (EM-6). Final guidance, drawn up by next summer, will address appropriate concerns that might have been raised over the next six months. Additionally, a report to Congress will be provided by June 1995, evaluating the risks to public health and safety posed by the conditions at weapons complex facilities that are addressed by compliance agreement requirements. This effort may uncover issues useful to address in the final guidance.

Attachment

Distribution:  
DOE Headquarters and Field elements

RISK ASSESSMENT, MANAGEMENT, AND COMMUNICATION  
AND  
PRIORITY SETTING

A. General Principles

1. These principles are intended to be goals for agency activities with respect to the assessment, management, and communication of environmental, health, and safety risks. Departmental programs should recognize that risk analysis is a tool -- one of many, but nonetheless an important tool -- in the regulatory tool kit. These principles are intended to provide a general policy framework for evaluating and reducing risks, while recognizing that risk analysis is an evolving process, and agencies must retain sufficient flexibility to incorporate scientific advances.
2. The principles in this document are intended to be applied and interpreted in the context of statutory policies and requirements, and Administration priorities.
3. As stated in Executive Order No. 12866, "In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction" [Section 1(b)(4)]. Further, in developing regulations, federal agencies should consider "...how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency" [Section 4(c)(1)(D)].
4. In undertaking risk analyses, programs should establish and maintain a clear distinction between the identification, quantification, and characterization of risks, and the selection of methods or mechanisms for managing risks. Such a distinction, however, does not mean separation. Risk management decisions may induce changes in human behaviors that can alter risks (i.e., reduce, increase, or change their character), and these linkages must be incorporated into evaluations of the effectiveness of such decisions.
5. The depth or extent of the analysis of the risks, benefits, and costs associated with a decision should be commensurate with the nature and significance of the decision.

B. Principles of Risk Assessment

1. Departmental programs should employ the best reasonable obtainable information from the natural, physical, and social sciences to assess risks to health, safety, and the environment.
2. Characterizations of risks and of changes in the nature or magnitude of risks should be both qualitative and quantitative -- that is, both descriptive and mathematical -- consistent with available data. The characterizations should be broad enough to inform the range of activities to reduce risks.
3. Judgements used in developing a risk assessment, such as assumptions, defaults, and uncertainties, should be stated explicitly. The rationale for these judgements and their influence on the risk assessments should be articulated.
4. Risk assessments should encompass all appropriate hazards to human health and the environment (such as acute and chronic risks, including cancer and non-cancer risks). In addition to considering the full population at risk, attention should be directed to subpopulations (including future generations) that may be particularly susceptible to such risks and/or may be more highly exposed.
5. Peer-review of risk assessments can ensure that the highest professional standards are maintained. Therefore, programs should develop procedures to maximize its use.
6. Departmental programs should strive to adopt consistent approaches to evaluating the risks posed by hazardous agents or events.

### C. Principles for Risk Management

1. In making risk management decisions with significant impact, programs should analyze the distribution of the risks and the benefits and costs (both direct and indirect, both quantifiable and non-quantifiable) associated with the selection or implementation of risk management strategies. Reasonably feasible risk management strategies including regulation, positive and negative economic incentives, and other ways to encourage behavioral changes to reduce risks (e.g., information dissemination), should be evaluated. Programs should employ the best available scientific, economic, and policy analysis, and such analyses should include explanations of significant assumptions, uncertainties, and the methods of data development.
2. Where programs have discretion to choose among alternative approaches to reducing risk, they should do so in the context of prevention programs and account for a broad range of relevant social and economic considerations such as equity, quality of life, individual preferences, and the magnitude and distribution of benefits and costs (both direct and indirect, both quantifiable and non-quantifiable).
3. Departmental programs should develop criteria and methods to evaluate the effectiveness of risk management decisions.

### D. Principles for Risk Communication

1. Risk communication should involve the open, two-way exchange of information between professionals, including both policy makers and "experts" in relevant disciplines, and the public.
2. Risk management goals should be stated clearly, and risk assessments and risk management decisions should be communicated accurately and objectively in a meaningful manner. To maximize public understanding and participation in risk management, programs should:
  - a. explain the basis for significant assumptions, data, models, and inferences used or relied upon in the assessment or decision;
  - b. describe the sources, extent, and magnitude of significant uncertainties associated with the assessment or decision;

- c. make appropriate risk comparisons, taking into account, for example, public attitudes with respect to voluntary versus involuntary risks; and
- d. provide timely, public access to relevant supporting documents, a reasonable opportunity for public comments, and a mechanism to incorporate public comments.

E. Principles for Priority Setting Using Risk Analysis

- 1. To inform priority setting, Departmental programs should seek to compare risks, grouping them, as appropriate, into broad categories of concern (e.g., high, moderate, and low) identifying the populations potentially at risk, and in context of uncertainty.
- 2. Programs should set priorities in managing risks. To set priorities, programs should take into account relevant management and social considerations such as different types of health or environmental impacts; individual preferences; the feasibility of reducing or avoiding risks; quality of life; environmental justice; and the magnitude and distribution of both short- and long-term benefits and costs.
- 3. The setting of priorities should be informed by internal agency experts and a broad range of individuals in state and local government, industry, academia, and nongovernmental organizations, as well as the public at large. Where possible, consensus views should be reflected in the setting of priorities.
- 4. Departmental programs should attempt to coordinate risk reduction efforts wherever feasible and appropriate.



**THE SECRETARY OF COMMERCE**  
Washington, D.C. 20230

FEB - 3 1995

Honorable George E. Brown, Jr.  
Ranking Minority Member  
Committee on Science  
United States House of Representatives  
Washington, D.C. 20515

Dear George,

This letter is in response to your request for the views of the Department of Commerce on Title III of H.R. 9, the Risk Assessment and Communication Act of 1995, and Title VII of H.R. 9, the Administrative Procedure Reform Act of 1995. The proposed legislation could adversely impact several important programs of the Department.

The legislation could negatively affect issuance of export control and other national security-related regulations promulgated by the Bureau of Export Administration (BXA). For example, subsequent to the Gulf War and the end of the Cold War, American foreign policy has focused on, among other things, preventing the proliferation of weapons of mass destruction, including chemical and biological weapons. To that end, export controls pertaining to items necessary for the production of these weapons are continually being enhanced. Many of these controls are the result of multilateral agreements. Title III of the proposed legislation could delay implementation of regulations that impose controls on the export of chemicals, biological organisms, and related equipment used in weapons production to the detriment of U.S. security interests. Further, delaying the regulations implementing the multilateral agreements would have a deleterious effect on American leadership in the effort to prevent proliferation of these weapons.

In addition, many rules are drafted in response to other U.S. multilateral export control obligations. We have no leeway in publishing such regulations, if we are to comply with our multilateral national security commitments. The expanded economic impact assessment and public hearing provisions of Title VII would delay implementation of rules, impairing U.S. compliance with multilateral security obligations. Such delay would undermine mutual national security interests, and in cases where a regulation provides for decontrol, would disadvantage U.S. exporters vis-a-vis their foreign competitors whose governments publish the multilaterally agreed-to changes more promptly (e.g., this Act would have delayed the implementation of the COCOM computer decontrol to 260 MTOPS).

Some of the regulatory changes we publish are to implement U.S. foreign policy objectives. Delays in publishing such rules would negatively affect our foreign policy agenda. For example, any time the U.S. Government wished to sanction a foreign entity for proliferation activities, the process would be delayed until the assessments, independent panel review and, possibly, public hearings were completed. Moreover, in certain instances,

export controls are imposed for foreign policy reasons in order to signal U.S. disapproval with the actions or policy of other countries, such as the embargoes on trade with Cuba and Libya.

With regard to the National Oceanic and Atmospheric Administration (NOAA), many of the principles contained in Title III of H.R. 9 are already fully incorporated in its basic statutory authorities or administrative procedures. For example, the requirements for improved risk assessment, sound scientific information, and the specific needs of small businesses are addressed in the Magnuson Fishery Conservation and Management Act through its mandate for review of supporting data by Scientific and Statistical Committees and industry-based Advisory Panels. Thus, NOAA's concerns with the Title III of H.R. 9 are not substantive, but procedural, in that the Act could require the development of duplicative procedures that would frustrate our regulatory programs and could increase the cost and delay the issuance of regulations necessary to provide the fishing industry with a stable and sustainable supply of natural resources.

I hope you find this information useful in your review of H.R. 9. The Office of Management and Budget advises that there is no objection to the submission of this report from the perspective of the President's program.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Brown', with a stylized flourish at the end.

Ronald H. Brown

cc: Hon. Robert S. Walker

## United States Department of State

Washington, D.C. 20520

FEB 8 1995

Dear Mr. Brown:

Thank you for the opportunity to comment on Title III of H.R. 9, the Risk Assessment and Communication Act of 1995. The thrust of this legislation appears to be aimed at regulations related to health, safety or the environment. The Department of State does not, as a general matter, play a key role in the development or implementation of such domestic regulations (although the Department does have a strong interest in ensuring that domestic regulation is sufficient to implement international commitments of the United States). For this reason, many of the questions attached to your letter did not appear to apply to the Department.

We are, however, troubled by the potentially broad reach of this legislation, which could be interpreted to apply to Department of State documents for which it clearly was not designed. The requirements of Section 3105 apply to "any" report to Congress or other document made available to the public. The relationship between this provision and Section 3103(b) of the Act, which states that the Act applies to risk assessments and characterizations prepared "in connection with Federal regulatory programs designed to protect human health, safety, or the environment," is unclear.

Conceivably, however, Section 3105 could be read to impose the specified principles for risk characterization and communication on, for example, the Department's travel warnings and consular information sheets. (Sample consular information sheets, for Peru and Colombia, are enclosed.) These documents are widely disseminated with the aim of informing American citizens before they travel of particular country conditions, including any health or environmental risks or political disturbances that could threaten safety, in a particular country. In addition, since "safety" is not defined, this legislation could be construed as reaching Department reports to Congress on national security issues such as the proliferation of weapons.

The Honorable  
George E. Brown, Jr.,  
House of Representatives.

-2-

The Office of Management and Budget advises that from the standpoint of the Administration's program there is no objection to the submission of these comments.

We hope that this information is helpful. Please do not hesitate to contact us if you have further questions.

Sincerely,

Wendy R. Sherman  
Assistant Secretary  
Legislative Affairs

Enclosures:

1. Consular Information Sheet for Colombia
2. Consular Information Sheet for Peru

# Travel Warning

United States Department of State

*Bureau of Consular Affairs*

*Washington, D.C. 20520*

For recorded travel information, call 202-647-5225.

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## Colombia

October 24, 1994

**Warning:** The Department of State warns U.S. citizens of the dangers of travel to Colombia. With the exception of several popular tourist areas, violence continues to affect a significant portion of the country. Recent kidnappings and attacks have targeted U.S. citizens and institutions. Additional information can be found in the Department of State's Consular Information Sheet on Colombia.

No. 94-045

This replaces the travel Warning for Colombia dated January 28, 1994, to incorporate updated information.



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Washington, DC 20520

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## Consular Information Sheet

### Colombia

October 31, 1994

**Warning:** The Department of State warns U.S. citizens of the dangers of travel to Colombia. With the exception of several popular tourist areas, violence continues to affect a significant portion of the country. Recent kidnappings and attacks have targeted U.S. citizens and institutions.

**Country Description:** Colombia is a medium income country with a diverse economy. Tourist facilities vary, depending on cost and area.

**Entry Requirements:** A passport and a return/onward ticket are required for stays of up to three-months. Minors (under 18) traveling alone, with one parent, or with a third party must present written authorization from the absent parent(s) or legal guardian, specifically granting permission to travel alone, with one parent or with a third party. This authorization must be notarized, authenticated by a Colombian Embassy or Consulate, and translated into Spanish. For current information concerning entry and customs requirements for Colombia, travelers can contact the Colombian Embassy at 2118 Leroy Place N.W., Washington, D.C. 20008, telephone: (202) 387-8338 or the nearest Consulate in Los Angeles, Miami, Chicago, New Orleans, New York, Houston or San Juan.

**Medical Facilities:** Medical care is adequate in major cities, but varies in quality elsewhere. Health problems in Colombia include the presence of cholera, though cholera is found largely in areas outside the cities and usual tourist areas. Visitors who follow proper precautions regarding food and drink are not usually at major risk.

Doctors and hospitals often expect immediate cash payment for health services. U.S. medical insurance is not always valid outside the United States. The Medicare/Medicaid program does not provide for payment of medical services outside the United States. In some cases, supplemental medical insurance with specific overseas and medical evacuation coverage has proven useful. For additional health information, travelers can contact the Centers for Disease Control's international travelers' hotline (404) 332-4559.

**Crime Information:** Based on Colombian government statistics, Colombia's per capita murder rate of 77.5 murders per 100,000 inhabitants is seven times higher than that of the United States. While narcotics and guerrilla related violence account for much of this, common criminals are responsible for 75 percent of the reported murders.

Minor crime is prevalent in cities, especially in the vicinity of hotels and airports. Theft of hand luggage and travel documents at airports is common. Taking illegal taxis, which are sometimes characterized by two drivers and irregular markings, may be dangerous. Attempts at extortion and kidnappings on rural buses are not unusual.

Many criminals use the drug "scopolamine" to incapacitate tourists, rob them, and then leave them unconscious, often for over 24 hours. The drug is administered in drinks (in bars), through cigarette smoke (in taxis), and in powder form (tourists are approached by someone asking directions, with the drug concealed in a piece of paper. The drug renders the person disoriented and powerless to resist the criminal's orders.

Another common scam is an approach to an obvious tourist by an alleged "policeman," who says that he is checking for counterfeit U.S. dollars and wants to "check" the foreigner's money. The person gives the criminal his/her money, receives a receipt, and the "policeman" disappears.

The loss or theft of a U.S. passport should be reported immediately to the local police and the nearest U.S. Embassy or Consulate. Useful information on guarding valuables and protecting personal security while traveling abroad is provided in the Department of State pamphlet, "A Safe Trip Abroad." It is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Also available from the same address is the Department of State publication, "Tips for travelers to Central and South America."

**Areas of Instability:** Violence in Colombia by criminal and guerrilla organizations is widespread. Travel by road outside the major cities is considered dangerous because of guerrilla activities in the countryside. As a result, the official travel of U.S. Government employees in Colombia is restricted as described below. The security situation in Colombia is volatile. U.S. citizens may consult the Department of State or the U.S. Embassy in Santa Fe de Bogota or the U.S. Consulate in Barranquilla to obtain the latest information about areas of instability in Colombia.

The following areas are considered particularly dangerous:

- Cundinamarca Department: rural roads.
- Colombia east of the Andes except the city of Leticia in the Amazonas Department and adjacent tourist areas in Amazonas.
- All of Antioquia Department (zone) including the city of Medellin.
- Most of the North Coast, except for the major tourist areas such as Santa Marta, Barranquilla, Cartagena, and San Andres.
- The Northern half of Choco Department, particularly the Uraba region, except for the tourist area of Capurgana.
- The Magdalena Medio region: The Magdalena River valley south to Tolima, including western Boyaca, eastern Caldas, and northwestern Cundinamarca.
- Rural Valle de Cauca Department and most of the Cauca River valley including the cities of Cali and Buenaventura, and the road between Cali and Buenaventura.
- Tolima Department south of Espinal, especially if traveling after dark.
- Road travel in Huila and Cauca Departments. The cities of Neiva and Popayan are considered to be safe if reached by air.

**Restrictions on U.S. Government Employees:** Because of security concerns, U.S. government employees assigned to Colombia or temporarily visiting in connection with their official government duties face severe restrictions on travel within Colombia. Travel by such personnel to the areas of instability listed above is generally limited to essential official functions and must be authorized by the Embassy. Requests by Embassy personnel for travel by car outside the Santa Fe de Bogota metropolitan area are considered on a case by case basis. The official travel of all U.S. government personnel traveling to Colombia must be approved in advance by the U.S. Embassy.

**Terrorist Activities:** Several terrorist or guerrilla groups are active in Colombia and U.S. interests are among their targets. Kidnapping for ransom or political purposes is increasing in Colombia. Several U.S. citizens have recently been kidnapped by guerrillas. In 1994, properties of churches identified with the U.S. were bombed in Bucaramanga, Cali and Medellin, and a bomb damaged a Coca-Cola bottling plant in Bucaramanga.

**Drug Penalties:** U.S. citizens are subject to the laws of the country in which they are traveling. Penalties in Colombia for possession, use and trafficking in illegal drugs are strict, and convicted offenders can expect lengthy jail sentences and fines.

**Firearms:** Colombian law prohibits tourists and business travelers from importing or bringing firearms into Colombia. The penalty for illegal importation and/or possession of firearms is 3 to 10 years in prison.

**Aviation Oversight:** In December 1991, the U.S. Federal Aviation Administration assessed Colombia's Civil Aviation Authority as in compliance with international aviation safety oversight standards for Colombia's carriers operating to and from the U.S. The same level of safety oversight would typically be applied to operations to other destinations. For further information, travelers may contact the Department of Transportation at 1-800-322-7873.

**Embassy Location/Registration:** Upon arrival U.S. citizens are urged to register with the Consular Section of the U.S. Embassy in Bogota at Calle 38 No. 8-61, telephone: (57-1) 320-1300 or the Consulate in Barranquilla at Calle 77, Carrera 68, Centro Comercial Mayorista, telephone: (57-58) 457-088, and to obtain updated information on travel and security within Colombia.

No. 94-255

This replaces the Consular Information Sheet dated September 2, 1994 by updating the warning and information on crime, terrorism and areas of instability.

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## Peru

July 20, 1994

**Warning:** The Department of State warns all U.S. citizens of the dangers of travel to Peru. With the exception of certain tourist areas, terrorist violence which has diminished over the past year continues to occur in many parts of the country. Foreign visitors have not been specifically targeted and tourist areas have generally been free of terrorist activity. Additional information can be found in the Department of State's Consular Information Sheet on Peru.

No. 94-029

This replaces the Travel Warning for Peru dated March 19, 1993, to reflect a diminishing of terrorist incidents over the past year.



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## Consular Information Sheet

### Peru

September 2, 1994

**Warning:** The Department of State warns all U.S. citizens of the dangers of travel to Peru. With the exception of certain tourist areas, terrorist violence which has diminished over the past year continues to occur in many parts of the country. Foreign visitors have not been specifically targeted and tourist areas have generally been free of terrorist activity.

**Country Description:** Peru has a developing economy. Tourist facilities outside of major cities and tourist areas may not be adequate.

**Entry Requirements:** A passport is required. U.S. citizens do not need a visa for a one-month stay. For current information concerning entry and customs requirements for Peru, travelers can contact the Peruvian Embassy at 1700 Massachusetts Avenue N.W., Washington, D.C. 20036, telephone: (202) 833-9860, or the nearest consulate in Los Angeles, San Francisco, Miami, Chicago, Newark, New York, Houston, or San Juan.

**Medical Facilities:** Medical care does not meet U.S. standards. Cholera and other infectious diseases, such as hepatitis, are present in Peru. Visitors who follow proper precautions about food and drink are not generally at risk. Malaria and other infectious diseases can be an added risk in some jungle areas. In addition, travel to high altitude areas can carry the risk of high altitude sickness, especially with rapid ascent.

U.S. medical insurance is not always valid outside the United States and the Medicare/Medicaid program does not provide payment of medical services outside the United States. In some cases, supplemental medical insurance with specific overseas and medical evacuation coverage has proven useful. For additional health information, the traveler can contact the Centers for Disease Control's international travelers' hotline at (404) 332-4559.

**Terrorist Activities:** With the exception of certain tourist areas (Arequipa, Cuzco, Ica, Iquitos, Paracas, Puerto Maldonado, Puno, and Trujillo), many parts of the country are designated as "emergency zones" (i.e. areas where the government has suspended certain constitutional rights). These zones are extremely dangerous because of terrorist and criminal activities. Despite the arrest of their key leadership in 1992, two insurgent organizations, Sendero Luminoso (Shining Path) and the Tupac Amaru Revolutionary Movement (MRTA) continue to carry out bombings and other terrorist attacks against a range of targets in Peru, principally Peruvian nationals, government installations, and banks, but also against U.S. as well as other foreign interests.

Terrorist violence has diminished in intensity over the past year but continues to affect a large part of the country. The cities of Lima and Callao remain under a state of emergency. With the exception of certain tourist areas which have been free of terrorist activity, terrorist bombings and shootings occur throughout Peru. Foreign visitors have not been specifically targeted by terrorist groups, however, the U.S. Embassy and other foreign embassies, commercial premises, and several hotels in Miraflores used by visiting business travelers and tourists have been damaged by package and car bombs.

**Emergency Zones:** The following areas have been designated as "emergency zones" by the Peruvian government: Apurimac Department, Ayacucho Department (except for the city of

Ayacucho proper), Huanacavelica Department, Huanuco Department, Junin Department, Lima Department, Pasco Department, San Martin Department, Ucayali Department (except for air travel to the city of Pucallpa), the La Convencion and Calco provinces within the Cuzco Department, the Huaraz, Carhuaz, Yungay, Recuay provinces of Melgar, Azangaro and Sandia within the Puno Department, the Huancabamba province within the Piura Department, and the Ucayali and Alto Amazonas provinces within the Loreto Department. These zones are extremely dangerous regions where both terrorism and violent crime are common. U.S. citizens who travel to or through designated "emergency zones" outside Lima, especially overland, are subjecting themselves to extraordinary risk.

**Crime Information:** Street crime such as pickpocketing and armed robbery, in or near hotels and residences, is very common. Robberies are a serious problem in Lima and in the tourist cities of Cusco and Iquitos. The majority of crimes are non-violent in nature and involve petty thefts by pickpockets and purse-snatchers. The threat of street crime is greatest in areas which attract large crowds. Over the last year criminals have become more brazen and have resorted to serious types of crime, such as smash and grab robberies, where thieves break car windows and steal any item within reach. Counterfeit U.S. bills in \$20, \$50, and \$100 denominations are common, and travelers should be extremely cautious when changing money with street side money changers. Paying close attention to one's personal belongings is an essential countermeasure to deter criminal activity.

The loss or theft abroad of a U.S. passport should be reported immediately to the local police and the U.S. Embassy. Useful information on guarding valuables and protecting personal security while traveling abroad is provided in the Department of State pamphlet, "A Safe Trip Abroad", which is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Also available from the same address is the Department of State publication, "Tips for Travelers to Central and South America."

**Drug Penalties:** U.S. citizens are subject to the laws of the country in which they are traveling. Penalties in Peru for possession, use and trafficking in illegal drugs are strict, and convicted offenders can expect lengthy jail sentences and fines.

**Adoptions:** All U.S. citizens wishing to adopt in Peru must use one of the agencies approved by the Peruvian government. For an up-to-date list of these agencies, prospective adopting parents are urged to contact the Department of State or the U.S. Embassy in Lima. For the foreseeable future, all adoptions will take place in Lima. The Peruvian government body charged with implementation of the new adoption laws, the Technical Secretariat for Adoptions, estimates that adoptive parents will need to remain in Peru for a minimum of 30 days and a maximum of 60 days. However, no adoptions have been completed under the new law and as a result it is uncertain how long prospective adoptive parents will have to remain in Peru to complete their adoptions. Adoptive parents should also know that foreigners carrying cash are identifiable targets for thieves.

The Peruvian Embassy in Washington, D.C. encourages prospective adopting parents to consult its staff for information on the adoption process. Additional information on Peruvian adoption proceedings and U.S. immigrant visa requirements is available from the consular section of the U.S. Embassy or by writing the Office of Citizens Consular Services, CA/OCS/CCS, Room 4817, Department of State, Washington, D.C. 20520, or by telephoning (202) 647-3712.

**Civil Aviation Oversight:** In February 1992, the U.S. Federal Aviation Administration assessed Peru's civil aviation authority as in compliance with international aviation safety oversight standards for Peruvian carriers operating to and from the U.S. The same level of safety oversight would typically be applied to operations to other destinations. For further information, travelers may contact the Department of Transportation at 1-800-322-7873.

**Embassy Location/Registration:** U.S. citizens, who travel to Peru despite the Department's travel warning, are requested to register with the consular section of the U.S. Embassy in Lima at Grimaldo del Solar 346. Miraflores, telephone: (011-51-14) 44-3621 or 44-3921 to obtain the latest travel and security information.

The U.S. Embassy is located at the corner of Avenidas Inca Garcilaso de la Vega and Espana, telephone: (011-51-14) 33-8000. There is also a consular agency in Cuzco at Avenida Tulumayo 125, telephone: (011-51-84) 23-3541.

No. 94-189

This replaces the Consular Information Sheet for Peru dated July 22, 1994 to add information on aviation oversight.



## United States Department of the Interior

OFFICE OF THE SECRETARY

Washington, D.C. 20240

February 13, 1995

Honorable George E. Brown, Jr.  
Ranking Minority Member  
Committee on Science  
House of Representatives  
Washington, D.C. 20515

Dear Mr. Brown:

Enclosed are answers to questions posed to us in your letter of January 20, 1995, concerning Titles III and VII of H.R. 9, titles concerning Risk Assessment and Cost Benefit Analysis for New Regulations, and Regulatory Impact Analysis.

Thank you for your interest. Please feel free to contact the Department if we can be of any further assistance to you on these important issues. We request that these responses be included in the record of Committee hearings on these issues.

The Office of Management and Budget advises that it has no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

Counselor to the Secretary and Deputy  
Assistant Secretary for Policy

Enclosure

## QUESTIONS AND ANSWERS

1.

Please identify the programs in the Department which would be subject to the requirements of the Risk Assessment and Communication Act of 1995 (Title III of H.R. 9), taking into account Title VII and other relevant sections of H.R. 9.

( The principal answers are contained in the answer to question 1.

Question 1 will be answered with a general discussion of Title III and of Title VII, followed by agency-specific responses from 3 Interior agencies, the Fish and Wildlife Service, the Office of Surface Mining, and the Minerals Management Service.)

A.

### Title III

It is important to note that most DOI regulatory activities do not address concerns which are subjected to "risk assessment" as that term is currently understood. Risk assessment is normally concerned with substance-specific issues such as epidemiological impacts, dose-response relationships, or estimates regarding the affects of exposure to certain substances, as concerns EPA. By contrast, DOI regulatory activities are generally related to broader land use issues or address impacts that, given the current state-of-the-art in relevant scientific disciplines, do not as readily lend themselves to the same sort of an evaluation. In this regard, factors related to protecting physical resources, public values, aesthetics and economic feasibility are generally far more pertinent than risk. Risk assessment methodologies generally do not take such factors into account because they are not used to address such issues.

The title's analytical requirements would be difficult to comply with and create numerous opportunities for litigation. For example, quantifying risks to the environment is always difficult because of the numerous variables and uncertainties inherent in any study. As agencies which perform risk analyses have indicated, this is true even in cases where reasonable amounts of data are available, as in the assessment of the impacts of potential toxic releases, given difficulties in measuring and predicting phenomena such as the probability of release, quantity and dispersion of substances, population exposure, etc. However, quantitative risk assessment is generally infeasible with respect to cases involving species and their habitat. Biologists are often reluctant to assess risks except on a qualitative basis, given data gaps and the lack of appropriate assessment methodologies.

Although the language of Title III (e.g., section 3104) references terms consistent with the more common understanding of risk assessment noted above, the coverage of the title is much broader.

Section 3103(b) applies the title's requirements broadly to all regulatory programs "designed to protect human health, safety, or the environment" rather than a specific subset of these programs which might be identified, for example, by criteria or by reference to specific statutes, and the exceptions noted in the subsection are extremely limited. Accordingly, by this standard it appears that all natural resource mandates administered by Interior are potentially subject to the title's requirements.

Given the definitions of "major rule" which apply to the risk analysis and peer review requirements in the new bill, the dollar thresholds for determining whether a rule is major have been revised to \$25 million with respect to the risk analysis requirement (section 3201(c)(2)) and \$100 million with respect to most of the peer review requirement (section 3301(h), except for \$25 million for peer review for section 3201(a)(5)(A) concerning the required assessment of cost and risk reduction or other benefits associated with each final rule). Although the original draft (September 1994) of the bill would clearly have applied to practically all Interior regulatory actions, these new dollar thresholds would appear to impact a significant number of DOI rules. In addition, the overlap between this title and Title VII is considerable and, given the lower threshold of the latter, could effectively reinstate the near-blanket applicability of the original bill.

Furthermore, Title III's reach could prove much broader, depending on how its non-monetary thresholds are interpreted. For example, some rules could arguably fall under the alternative qualitative standards, the "major increase in costs" or "significant adverse effects" provisions in section 3201(c)(2) for conducting risk assessments. It is reasonable to expect significant and perhaps frequent litigation in this regard.

Nonetheless, even assuming that a minority of rules are impacted, there would be substantive -- and severe -- affects on a number of resource management mandates. For example, regulations promulgated under the Migratory Bird Treaty Act (MBTA) would be subject to both the risk analysis and peer review processes. It should be noted that the MBTA prohibits the hunting of migratory birds (e.g, ducks) unless authorized by the Secretary of the Interior through rulemaking. The regulations that allow hunting are promulgated annually and are based on the ability of bird populations to maintain sustainable levels despite harvesting. The process for developing these regulations is well established and involves coordination with States, wildlife organizations, and the public.

The requirements of Title III, when combined with other provisions in H.R. 9, eliminate the waterfowl hunting season, with considerable adverse economic and social impacts. Under the Migratory Bird Treaty with Canada, no hunting of migratory birds may occur between March 10 and September 30 of each year. The species population data necessary to set seasons and bag limits is not available until late July of each year. From that starting point, the requirements of H.R. 9 could not be met in time to permit a hunting season, as illustrated in the attached case study.

In addition to this example, other programs would probably be affected, especially when efforts are undertaken to revise rules comprehensively so as to promote efficiency and reduce burdens on the public. Examples could include comprehensive revisions of coal mining rules or those concerned with energy development, natural resource damage assessments under CERCLA, the irrigation drainage program administered by the Bureau of Reclamation, and the development of oil and gas on the OCS by the Minerals Management Service.

## B.

### Title VII

Title VII would substantially increase the analytical resources and time required for Interior agencies to promulgate rules. The most significant impacts on regulatory efforts would result from the new "major rule" definition and a new requirement to review all currently effective rules. Additionally, Title VII would impose new requirements that could increase the time to promulgate rules by many months.

There bill specifies 23 issues that require coverage in the regulatory impact analysis. The bill would give interest groups the ability to seek injunctions against new regulations on the ground that the RIA did not adequately address an issue they believe to be important. Moreover it is likely that case law would ultimately require ever-increasing refinements to the analysis. In addition, the interaction between these requirements and the decisionmaking factors included in specific environmental mandates will be difficult for agencies to sort out, particularly in cases of apparent conflict, and almost certainly ensure frequent litigation and potentially conflicting judicial determinations.

As in the case of several other titles, Title VII, while ostensibly focusing on procedure, is a *de facto* amendment of significant environmental protection laws. Title VII would amend the Administrative Procedure Act and certain Executive Orders regarding regulatory rule making procedures. The most significant change under this legislation would be to establish a new definition for a "major rule." According to this new definition, a major rule would be any regulatory action that affects more than 100 persons or that requires an expenditure of more than \$1 million by any person.

Current guidelines define a major rule generally as any regulatory action with an annual effect on the economy of \$100 million or more. The new definition would classify virtually all Federal regulatory actions as major rules. As such, these rules would require detailed regulatory impact analyses even though the vast majority of them are not controversial.

Another significant change would be to reinstate and broaden the regulatory provisions of Executive Order 12291. This Executive Order was revoked by the Administration on September 30, 1993, and replaced by Executive Order 12866, which mandates a rigorous yet rational process for promulgating rules. The major effect of the bill would be to require agencies to initiate reviews of all currently effective rules and to perform regulatory impact analyses on those that would be classified as major. These analyses would need to conform to the requirements specified in Titles VI and VII, which are much more detailed than those contained in the current guidelines, and include requirements to quantify risks, assess economic costs (including compliance costs) and demonstrate that the rule provides the least costly or intrusive approach. Moreover, agencies would be required to postpone the effective dates of pending major rules in order to perform the regulatory review. Exemptions would be provided only for emergencies and statutory or judicial deadlines.

Additionally, Title VII would impose two new requirements that would significantly increase the time required to promulgate rules. First, agencies would be required to publish a "notice of intent to engage in rule making" at least 90 days before publication of the general notice. Second, upon request by more than 100 individuals, agencies would be required to extend the public comment period by 30 days and hold hearings. Therefore, at least 120 days could be added to the time required to promulgate rules, in addition to any extra analytic time that would be imposed by this title or by Title III. Further, agencies will have to determine whether commenters are "acting individually" or in concert, a task that will prove difficult and invite litigation.

There is considerable overlap between the requirements of this title and Title III. For example, this title also includes a risk analysis requirement, and those related to cost/benefit and cost-effectiveness analysis are also largely duplicative. This will further increase the potential for confusion and litigation. A total of 257 rules are scheduled for review or development by the Department between October 1994 and April 1995. Of these, 18 have been determined to be significant under Executive Order 12866. Significant rules generally undergo more detailed regulatory analyses than other rules, but far less than would be required under Title VII. Assuming that the major impact of Title VII would fall on rules currently not determined to be significant, a total of 239 rules would require increased regulatory analysis. This number is conservative since, as noted above, the regulatory analysis for many of the

rules that are currently designated significant is not as detailed as that required under Titles III and VII. In summary, whereas now only a small fraction of the Department's rules now require detailed analyses, the low threshold established in this title would now affect virtually all rulemakings.

Estimates for conducting regulatory analyses range from \$15,000 to \$500,000 per rule. These estimates are conservative since they do not account for the analytical costs of calculating indirect effects under Title VI. Assuming that most regulatory actions would be completed within one year, regulatory analysis costs for the Department would likely increase by a minimum of \$3.6 million per year for new rules alone, even in a best-case scenario; in fact, some individual rules could require resources of this magnitude. The Department would also be required to review all currently effective rules. A total of 53 rules were amended or rescinded by the Department when Executive Order 12291 was originally implemented in 1981. Assuming a like number of revisions under Title VII, the Department would likely incur at least \$800,000 in additional regulatory analysis costs. Again, however, this estimate is also conservative since it does not account for the analytical costs associated with regulations that would not be revised.

The increased analytical detail and the "notice of intent to engage in rule making" requirement would be expected to substantially increase the time necessary to promulgate rules. For example, the Minerals Management Service estimates that these requirements would increase the time required to promulgate rules by 25 percent. This increased time requirement could invite litigation. In one case involving CERCLA regulations, the Department has been sued for taking too much time in its rule making efforts. Such cases would be expected to occur more frequently.

An additional problem with potentially serious consequences for natural resources such as parks and wildlife protection relates to the title's requirements to monetize benefits. Measuring costs is generally easier than measuring benefits, but this disparity is especially acute with respect to natural resources. Measuring the benefits of protecting an endangered species, for example, presents major methodological difficulties and can prove extremely costly (e.g., as exemplified by the difficulties in assessing the dollar value of wildlife impacts related to the Exxon Valdez incident). Further, the utility of existing measurement techniques (e.g., contingent valuation surveys) is controversial among both economists and resource professionals.

Accordingly, the requirements present numerous procedural obstacles and opportunities for litigation that could drastically impair efforts to protect park resources, and could also bring endangered species listing and management activities

to a standstill.

- C. The following discussion addresses some specific impacts of the bill on DOI agencies.

## **FISH AND WILDLIFE SERVICE**

### **Title III - Risk Assessment and Cost-Benefit Analysis**

#### **Subtitle B - Analysis of Risk Reduction Benefits and Costs**

Assuming that most Service regulations would be considered as "designed to protect the environment," some listings under ESA might meet the \$25 million annual economic impact threshold criteria of this section and for peer review of cost and risk reduction analysis of final rules, and a few could meet the \$100 million threshold for peer review.

With respect to Migratory bird hunting regulations, the subtitle provides no guidance as to what risks are to be evaluated - risks to the ducks, or to the hunters, or to both. These regulations do clearly meet the \$25 million impact standard of the subtitle and the \$100 million impact trigger for peer review.

**These requirements, along with other provisions of the bill, would delay the issuance of those regulations so as to eliminate the waterfowl hunting season. The following illustrates why this would occur.**

- 1) Cost-benefit and risk analyses - If these are begun as soon as final data available in late July, they will take three months to complete. (This presumes that we have undertaken initial studies, for \$250,000 to \$300,000, on the regulations the year prior to the bill becoming effective, so a shorter follow-on analysis can be done; otherwise, studies could take 6 - 12 months).
- 2) Provide completed draft regulation to Chief Counsel for Advocacy, Small Business Administration, 30 days prior to publication in Federal Register - delays publication of draft regulations to early December.
- 3) Provide 30-day extension of the public comment period when requested by any 100 persons - moves end of comment period to late January. The process could be extended further if public hearings are required.
- 4) Peer review of cost-benefit and risk analysis for final rule - takes until the end

of February. Treaty prohibits hunting between March 10 and September 30.

With respect to endangered species, it is highly unlikely that any realistic data as to risks to the species with or without the listing are available or can be readily derived, if this is indeed the "risk" that would be required to be analyzed. Few, if any, of the specific criteria in the bill relate to most Service regulatory authorities, so they provide little guidance, yet at the same time, given the broad reach of the bill, they also provide significant litigation opportunities.

Similarly, cost-benefit analyses could be required in a number of cases, but there is little available data on either - on costs, because most impacts would be to future actions which are not readily predictable now; and on benefits, because most benefits from the continued existence of a species are intangible - they are not traded in the market, and thus their dollar value cannot be estimated directly from existing market data. Past efforts to monetize environmental values have been highly controversial, and new efforts would almost certainly be litigated.

Inasmuch as the ESA specifically precludes the Service from taking non-biological factors into account in making listing decisions, and there has never until now, been any request for costs or benefits from refuge hunting or trade regulations, we have no existing capability to determine what economic impacts might result from any such regulations.

The Service would have to incur considerable expense -- largely for the employment of consultants -- to acquire data from which to make estimates of costs and benefits, the latter by means which themselves are not generally accepted, and then incur further expenses to subject those conjectures to peer review under section 3301.

We are now required to consider costs in cases where critical habitat is designated for listed species. Based on this experience, we estimate that a cost-benefit analysis and a risk analysis for Service regulations would each cost at least \$125,000 to \$150,000 per regulation, and take between six months and one year to conduct. In cases where the regulations must be revisited or reissued regularly, we estimate the subsequent cost-benefit and risk analyses cost between \$20,000 and \$50,000, and take three months to conduct.

Formal peer reviews generally take from 4 to 6 months, with costs highly variable depending upon the academic standing of the reviewers. We believe that if extensive advance arrangements and coordination were undertaken, and additional compensation

provided to the reviewers, it might be possible to complete a formal peer review in one month. We do not have cost estimates for this.

We estimate we will be issuing 100 regulations for listing under the ESA per year for the foreseeable future; we are not able to determine now which ones might cross the threshold of this section. For those that do, the additional costs will be as noted above.

There is also a conflict between the explicit requirements of ESA section 4(b)(1)(A) that listing decisions be made "solely on the basis of the best available scientific and commercial data" [in this context, "commercial" means "wildlife trade"], and the requirements of this title, particularly sec. 3201(a)(5)(C). Although H.R. 9, if enacted, would be a "later in time" statute than ESA, litigation could well result over this point.

Finally, ESA has specific requirements, which the courts have enforced, to issue listing proposals and make final decisions within specific time frames. The Service could not comply with those deadlines for listings which required cost-benefit and risk analyses. It is unclear how the conflicts between the requirements of this bill and specific environmental or natural resource management statutes will be resolved, but extensive and costly litigation appears certain.

#### Title VII - Regulatory Impact Analyses

Sec. 7004(b) defines "major rule" for this title as one affecting more than 100 persons or requiring the expenditure of more than \$1,000,000 by any non-Federal entity. Virtually all Service regulations would be defined as a "major rule" under this standard.

Many new requirements are established for major rules. The net effect of the requirements will be to substantially increase the costs and time needed for issuance of virtually any Service regulation. For example, the requirement in sec. 7004 that proposed rules contain a list of fees and fines for required permits and licenses will require the Service to maintain an up-to-date list of all State hunting license requirements and penalties for both the national migratory bird hunting regulations and the opening or revising of hunting on any refuge.

The requirements for cost-benefit analyses are particularly troublesome, inasmuch as in many cases benefits from Service actions, such as opening an area to hunting, are not quantifiable by any generally accepted methods. Past efforts to monetize environmental values have been highly controversial.

The requirements in sec. 7004, including particularly cost-benefit analyses and determinations that a proposed rule represents the least costly approach, create virtually unlimited opportunities for litigation as to whether regulations are in compliance. For example, it might be particularly inviting for anti-hunting groups to sue over the adequacy of the non-biological data required by this title for any hunting-related regulation.

Endangered Species Act listings appear not covered by the requirements of section 7004 due to the exemption from E.O. 12291 and the Regulatory Flexibility Act previously referenced. Since H.R. 9 specifically reinstates E.O. 12291 "as in effect on September 23, 1993" -- at which time ESA regulations were unquestionably exempt from its provisions -- rather than imposing the requirements of the E.O. "de novo" as provisions of the bill, it would certainly seem that the ESA listings remain exempt from the reinstated E.O.

However, the mandatory 30-day extension of comment periods provided in section 7003 would be applicable, as this comes from an amendment to the Administrative Procedure Act. This could cause yet more conflicts with explicit time deadlines in the ESA for issuing proposed and final listings.

If the ESA listings were brought within the scope of E.O. 12291 as revised by this bill, each of the 100+ annual listings would be subject to the requirements for cost-benefit analyses, with a delay of six months to one year and a minimum cost of \$125,000 to \$150,000 per regulation, or additional costs of at least \$12.5 million to \$15 million annually. The FY 1995 appropriation for listings was \$8,077,000.

Extensive litigation could also be expected, on several fronts. As noted previously, there is no generally accepted formula for monetizing environmental benefits; each Service efforts to do so in compliance with these requirements could be subject to suit by opponents of the listing(s) in question, or opponents of whatever method was used to calculate the benefits. The adequacy of the Service's compliance with the other requirements of the revised E.O. would also be subject to suit. In addition, the previously-noted conflict between the general requirement in sec. 7004(c)(11) that regulations include an evaluation of how their benefits outweigh their costs and the specific requirement of the ESA that only biological data be used to make a listing decision would also likely subject the Service to suit no matter which provision is complied with.

## OFFICE OF SURFACE MINING

Almost all of OSM rulemaking activity would likely qualify as a major rule and be impacted by Title III and all rules would certainly be impacted by Title VII. Such rules likely to be impacted include:

- VALID EXISTING RIGHTS
- AVS PERMIT INFORMATION
- COAL WEIGHT DETERMINATION
- SUBSIDENCE
- ABANDONED COAL REFUSE SITES
- AML GRANT PROCEDURES
- COAL REMINING
- DEFINITION OF COAL
- AFFECTED AREA
- COAL MOISTURE
- CONTEMPORANEOUS RECLAMATION
- NOTIFICATION AND RIGHT OF ENTRY REQUIREMENTS
- ARIZONA FEDERAL PROGRAM
- PROHIBITIONS
- RAILROADS

OSM cannot estimate the additional time and resources needed to comply with the rulemaking procedures outlined in the proposal. OSM would not be able to publish rules in a timely manner while complying with the Act, and would be required to devote additional scarce resources to the effort to implement the new requirements.

No formal risk assessments have been prepared by OSM during the last fiscal year. The Departmental Manual provides guidelines on cost-benefit analyses in 318 DM 7. OSM is required to prepare a cost/benefit analysis for all major significant rules (having an impact of \$100,000,000 or more) and is currently in the process of preparing one required by Executive Order 12866. There are currently no guidelines for risk assessment, risk characterization or peer review.

It is impossible to estimate the cost to comply with the peer review requirements of section 3301. However, the majority of OSM rules would need to go through the peer review process, requiring at least an additional year to complete each final rulemaking. Peer reviews may be subject to FACA.

Currently, only one rule has required a detailed cost/benefit analysis, comparable to that envisioned in this bill. Under the definitions in Title VII of H.R. 9, almost all of

OSM's rules would be classified as "Major" and would require a cost/benefit and risk assessment. No estimate is available as to the dollar amount required to administer this title. At a minimum, OSM would either have to hire several new professional staff in addition to being required to contract for specialized analytic expertise for some aspects of its regulations.

Extensive procedures would be required to comply with the Act. Procedures would need to be created to implement all aspects of Titles III and VII. All recent gains to streamline the rulemaking process would be reversed.

## MINERALS MANAGEMENT SERVICE

### Title III

This Title would apply to many, if not most MMS regulations for offshore oil and gas operations, including safety, environmental, and resource conservation requirements.

Title III could be very difficult and costly to administer, depending on the eventual nature of the risk assessments and peer reviews. If this title delays promulgation of rules, as it most certainly will, it will actually increase the cost and regulatory burden on industry.

Risk assessments are no panacea. While in some cases the analyses could be useful in identifying statutory mandates that are not cost-effective, they are often limited by the availability of data and/or current science and in many cases are inferior to the collective judgements of recognized experts. Problems include: the lack of consensus on appropriate methodologies; difficulties in making value judgements re controversial issues that do not lend themselves to resolution via risk assessment (e.g., human life, beaches, marine life, etc.); problems in comparing "apples and oranges" (e.g., the extent to which data for one type of value equates to that for another); determinations of the effects of new technologies; and general concerns related to cost and complexity. Further, risk assessments can be easily manipulated to produce the desired result. In addition, although the apparent intent of the bill is to avoid new information collection requirements on industry (see Title V), that may be the only means by which to gather reasonably reliable data for performing risk assessments.

Congress should also be aware that industry generally supports OCS regulations, since they are largely performance based, incorporate industry standards and enhance the value of those standards through public review and MMS acceptance. The rules facilitate planning and orders to contractors. Also, offshore operators are concerned about marginal companies that might otherwise "cut corners" and significantly impact the reputation of the entire industry.

#### **CASE EXAMPLES:**

1. The title would duplicate and delay review of rule revisions that incorporate the latest version of industry standards, which have already been peer-reviewed and accepted by the industry.
2. The pipeline valve rule would have saved at least 5 lives over the last 10 years. Risk assessment procedures provide no clear guidance on how to balance human life against regulatory compliance costs.
3. The proposed Hydrogen Sulfide rule will reduce the regulatory burden on industry, but the bill's analytical requirements would delay its promulgation.
4. Public Law 103-426, enacted 10/31/94, pertains to negotiated agreements for the use of OCS sand, gravel, and shell, and includes the term "shore protection" as well as such terms as "beach or coastal wetlands restoration." If a rule were to be promulgated to implement the new law, it could be construed as pertaining to a Federal regulatory program designed to protect human health, safety, or the environment, even though it is actually pertains to the process of handling a negotiated agreement. This example is likely to be only one of a number of "gray area" issues that may invite litigation.

#### **TITLE VII**

Virtually all MMS regulations would be defined as "major" under the revised definition in title VII. The bill would add substantial administrative costs. "Major" rules, requiring full regulatory impact analyses, are currently the exception within MMS, but the bill would result in virtually all rules being "major."

The title also adds an additional bureaucratic step to the regulatory process: the notice of intent to publish a rule, containing the information developed in the regulatory impact analysis. The language of the bill and E.O. 12291 is not clear with respect to

the review of existing rules. The bill would create a substantial new work load if all existing "major rules" are required to undergo a regulatory impact analysis. Again, virtually all existing regulations would be considered major under the new definition and would have to be addressed. MMS periodically reviews its regulations to eliminate or update those that are outdated, duplicative, or inefficient. The detailed analysis of current regulations that may be called for in this bill would require additional resources and detract from rule writing - possibly increasing the time needed for publishing rules (including those designed to reduce the regulatory burden). The notice of intent requirement thus will impose delays and costs in changing regulations - including those that would reduce regulatory burdens.

**CASE EXAMPLES:** The definition of "major rule" will require a detailed regulatory analysis for all Royalty Management Program regulations. These would include:

- Federal Gas Valuation
- Indian Gas Valuation
- Payment Responsibility
- Oil and Gas Transportation and Processing
- Coal Washing and Processing
- Method of Payment EFT
- Administrative Offset
- Credit Adjustments

Under the new criteria for determining that a rule is "major," a new regulation changing the address to which royalty payments are sent would be considered major because it effects more than 100 people, even though there is no substantive change in the regulation.

For the Offshore program, every rule currently under consideration would meet the minimum definition for a major rule. These rules include:

- OPA-90 spill response
- OPA-90 financial responsibility
- Hydrogen sulfide
- Gas measurement
- Production safety
- Restrictions on burning or flaring
- Bonding (phase II)
- Training
- Modified bidding systems

A specific example from the offshore program is a regulation that has broad support from industry. When we issued our interim final rule on Oil Spill Response Plans mandated by the Oil Pollution Act (OPA-90), industry was very appreciative. Our guidance allowed industry to comply with OPA-90, which required Spill Response Plans by a given deadline. Under the new bill, this action issuing the interim final rule would have been delayed by the analyses required by this and other titles. This delay could have caused our constituents to be not in compliance.

All rules currently in process would have to be reexamined under the criteria for major rules. If rules are to meet current schedules for publication, additional resources would be needed to conduct analyses. If no additional resources are available, each rule could be expected to take approximately 25% more time to finish.

## QUESTIONS 2-9

2. Using the definitions of "risk assessment" and "risk characterizations" set out in section 3107 of the Act, how many risk assessments and risk characterizations were prepared by, or on behalf of, the programs in the Department over the last fiscal year? Of those, how many would be considered to be a "screening analysis" exempted under section 3103(b)(2)?

A. See answer to #1. It is not apparent that any such analyses have been prepared.

3. Please describe the Department's present practices, including references to any published guidelines or procedures, relating to risk assessment, risk characterization, cost-benefit analysis, or peer review.

A. See answer #2 with respect to risk analysis or risk characterization.

With respect to cost-benefit analysis, the Department has implemented the requirements of E.O. 12866, which address this subject as a requirement for significant rulemakings. In addition, cost-benefit related considerations are addressed in other guidance documentation such as the Bureau of Reclamation's cost-benefit guidance for water projects, BLM's guidance re NEPA analysis for onshore oil and gas leasing, and natural resource damage assessment regulations and related guidance documentation issued by the Department's Office of Environmental Policy and Compliance. The Fish and Wildlife Service performs status reviews under the endangered species programs, but these do not really constitute risk assessments as the term is normally understood (see answer to question #2).

4. If enacted into law, how would the Act affect the Department's present practices as described in question 3? If compliance with the Act would require additional resources in carrying out such practices, please estimate the additional resources (in terms of dollars and personnel) that would be required to carry out the provisions of the Act.

A. It is extremely difficult to provide a reliable estimate in this regard. If an estimate based on an average cost per rule was derived, a total of several million dollars per year might be reasonable. However, an average cost basis could prove extremely inaccurate, since a single rule could engender complex issues that might result in significant costs. Further, the costs could be exponentially higher in light of Section 3201(c)(1), which mandates the consideration of both direct and indirect costs. The methodological challenges associated with assessing indirect costs would be daunting and likely require the develop of new (or drastic refinement of existing) economic models and major data collection efforts. Further, such assessments would almost certainly be litigated.

5. How does the Department obtain the information it uses to prepare risk assessments, cost-benefit analyses, or risk characterizations? Does the Department rely in part upon the private sector in providing the information needed by the Department to conduct such assessments or analyses? If so, would the Act require the Department to obtain additional information from the private sector in order to comply with the Act's requirements?

A. The Department must rely on outside expertise for many of its technical analyses. FWS and other natural resource trustees under CERCLA rely almost exclusively on private contractors for injury determinations and damage assessments. The analyses contained in many EISs are also contracted out to private parties. Such analyses would require risk assessments under the provisions of Title III. In many cases, the assembly of significant data bases would be required to perform the analyses. In the case of MMS, for instance, the data to conduct these risk assessments would most likely come from increased information collection from industry. Further, the lack of established methodologies for performing these analyses (in general and with respect to Interior regulatory mandates) could add significant additional costs.

6. Please identify the regulations expected to be proposed or promulgated in the next two years which would require a Regulatory Impact Analysis under Title VII, an analysis of risk reduction benefits and costs or a certification under Subtitle B of Section 3201, or a peer review under Section 3301. What additional procedures would the Department be required to follow to issues such regulations if the Act was enacted into law? Would the Act permit judicial review of agency actions beyond

what is presently permitted under the Administrative Procedure Act. Please estimate the additional time and resources that would be necessary to complete the expected rulemaking following the required procedures. If the Department is subject to court-ordered or statutory deadlines for completion of any such regulations, can the Department comply with the Act and still meet such deadlines?

A. With respect to Title VII, virtually all regulations would be impacted given its definition of "major rule." The precise number of rules involved is difficult to estimate, but the current period provides some basis in this regard. For example, between October 1994 and April 1995, DOI projects a total of 257 rules scheduled for review or development. If Title VII's requirements applied, at least 239 -- or 93 percent -- of these rules would have to undergo the mandated analyses. Costs are likewise difficult to estimate, although the answers to question #4 and #7 address some of the major concerns in this regard.

It appears that the Title would provide many new opportunities for litigation. Further, in so doing, the results could ultimately color the substance of risk analysis and cost benefit analysis. This could actually retard progress in advancing scientific and economic considerations in the regulatory process.

7. Are the requirements of section 3105 for risk characterization (taking into account the definitions in 3106) consistent with the Department's understanding of sound scientific principles for risk assessment and risk characterization? Would the requirements of section 3105 preclude the Department from considering any information, models, or assumptions in assessing or characterizing risk? How would the Department be able to take into account risks to special subpopulations which have higher susceptibility than "average"?

A. As noted in answer #1, risk assessment (as the term is commonly understood) generally addresses concerns which are not normally regulated under DOI mandates, as opposed to statutes implemented by agencies such as EPA, FDA, Labor and Transportation. Consequently, as the question appears to suggest, implementation of Title III's requirements would present significant methodological challenges. It should be noted that even in cases where risk assessment is already practiced and where reasonable amounts of data are available, as in the case of toxic releases, difficulties in measuring and predicting phenomena such as the probability of release, quantity and dispersion of substances, population exposure, etc., and numerous other variables and uncertainties present major analytical challenges. However, application of the requirements to Interior mandates would be even more difficult. For example, with respect to cases involves species and their habitat, biologists have found it extremely difficult to assess risks, given their diffuse and uncertain nature, except on a



U.S. Department of  
Transportation  
Office of the Secretary  
of Transportation

GENERAL COUNSEL

400 Seventh St., S.W.  
Washington, D.C. 20590

February 2, 1995

The Honorable George E. Brown, Jr.  
Ranking Democratic Member  
Committee on Science  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Brown:

This is in response to your request for information concerning Title III of H.R. 9, the Risk Assessment and Communication Act of 1995. The Department of Transportation is concerned that the complex and unwieldy requirements in Title III could undermine our ability to respond quickly and effectively to transportation safety issues. Although Title III appears designed to address the types of scientific and environmental analyses commonly performed by agencies such as the Food and Drug Administration and the Environmental Protection Agency, it would apply broadly to all agencies, including the Department, that regulate public safety.

Title III's rigorous requirements for risk assessments, cost-benefit analyses, and independent peer review would apply to virtually all the rulemaking actions the Department undertakes. These requirements would cause substantial delay and result in increased costs to Government, industry and, ultimately, the taxpayer. We are also concerned that these provisions have the potential for unnecessary and protracted litigation, resulting in additional delay and expense. Taken together, the provisions in Title III and Title VII could have adverse impacts on a number of the Department's safety programs. For example, these provisions could delay rulemakings in progress to make commuter airlines meet the safety requirements of larger airlines and to improve service to travelers by providing clear notice when one airline trip will involve some travel on a small airliner. These provisions would delay even rules that are cost-beneficial and strongly supported by all interested parties, such as the high-mounted rear stoplight rule issued several years ago. The National Highway Traffic Safety Administration estimates that a single year's delay in implementing a new vehicle safety standard concerning head impacts in vehicle interiors would result in loss of 1150-1400 lives over 20 years.

2

The responses to your specific questions are provided in the enclosure, and we have assembled as full a response as possible in the limited time available. I hope that this information is helpful.

The Office of Management and Budget advises that, from the standpoint of the Administration's program, there is no objection to submission of these views for the consideration of Congress.

Sincerely,

A handwritten signature in dark ink, appearing to read "Stephen H. Kaplan", is written over the printed name.

Stephen H. Kaplan

Enclosure

Department of Transportation Responses Concerning Title III (H.R. 9)

QUESTION 1. Please identify the programs in the Department which would be subject to the requirements of the Risk Assessment and Communication Act of 1995 (Title III of H.R. 9), taking into account Title VII and other relevant sections of H.R. 9.

RESPONSE: Section 3103(b)(1) of the bill provides that, with certain exceptions, the risk assessment requirements of Title III apply to all health, safety, and environmental regulatory programs. This title would apply primarily to safety programs in the case of the Department of Transportation (DOT). The following are the major DOT safety programs to which Title III would apply:

- The aviation safety program of the Federal Aviation Administration.
- The maritime safety programs of the Coast Guard.
- The motor carrier safety program of the Federal Highway Administration.
- The pipeline safety program and hazardous materials safety program of the Research and Special Programs Administration (RSPA).
- The space launch safety program of the Office of Commercial Space Transportation.
- The motor vehicle safety program of the National Highway Traffic Safety Administration.
- The railroad safety program of the Federal Railroad Administration.

In addition, some DOT administrations issue environmental regulations. These regulations typically implement statutory directions (e.g., Coast Guard rules implementing the Oil Pollution Act of 1990; FHWA rules protecting park lands, recreation areas, wildlife refuges, and historic sites) or attempt to balance the interests of parties having an interest in the environmental effects of transportation (e.g., FAA rules concerning airport noise mitigation). Rules of this kind usually do not involve risk assessments in the sense discussed in H.R. 9.

QUESTION 2: Using the definitions of "risk assessment" and "risk characterizations" set out in section 3107 of the Act, how many risk assessments and risk characterizations were prepared by, or on behalf of, the programs in the Department over the last fiscal year? Of those, how many would be considered to be a "screening analysis" exempted under Section 3103(b)(2)?

RESPONSE: The difficulty posed by much of Title III for DOT is that risk assessment and risk characterization, as defined in section 3107, are directed toward analytical and predictive problems rarely encountered in the Department's safety rulemaking process. Unlike the rules of the Environmental Protection Agency (EPA) or health agencies, DOT safety rules seldom are based on a quantification of the risks of toxicity or exposure for exposed individuals, populations, or resources. RSPA does have a Risk Assessment Prioritization (RAP) program that uses a mathematical model to evaluate annually each pipeline safety and environmental protection issue, the potential solutions to each issue, and the appropriate corresponding actions to reduce risk. The key goal of the RAP program is to develop a credible and achievable agenda that will allocate our resources to tasks with the greatest potential to improve public safety and protect the environment without causing an undue burden on the pipeline industry. In addition, our Office of Commercial Space Transportation has a relatively small program in this area.

DOT agencies typically learn, through experience of or data about real world transportation safety problems (including analysis of accidents), how a particular practice, piece of equipment, design, or human factor may affect the safe operation of aircraft, ships, motor vehicles, trains, trucks, or buses. Thus, the DOT agencies have data about actual deaths, injuries, and property damage resulting from particular transportation safety problems. Based on this information, the DOT predicts future risks and takes regulatory steps to increase safety through modification of practices, training of personnel, improvements in technology, etc.

Using the definitions set forth in this bill, however, the Department has prepared few risk assessments or characterizations in the last or any other fiscal year. It would create enormous difficulty if this EPA/FDA model of conducting risk assessments and characterizations were imposed on DOT safety rulemakings, which they simply do not fit. Section 3201 appears to have the effect of forcing us to conduct these assessments in rulemakings that would have a \$25,000,000 annual impact, as many DOT rules have.

QUESTION 3: Please describe the Department's present practices, including references to any published guidelines or procedures, relating to risk assessment, risk characterization, cost-benefit analysis, or peer review.

RESPONSE: For the reasons noted above, there are no formal DOT procedures concerning risk assessments, risk characterizations, or peer review. The Department's Regulatory Policies and Procedures, which have been in place since 1979, require economic evaluations (which include cost-benefit analysis for those with "major" impacts) for all rulemaking. A copy is attached. In addition, the Department has produced and used guidance for conducting cost-benefit studies of rules. These are lengthy documents. We can copy them subsequently if you believe it is useful to do so.

**QUESTION 4:** If enacted into law, how would the Act affect the Department's present practices as described in question 3? If compliance with the Act would require additional resources in carrying out such practices, please estimate the additional resources (in terms of dollars and personnel) that would be required to carry out the provisions of the Act.

**RESPONSE:** As noted above, to force DOT safety rulemakings into an ill-fitting template designed for other types of rulemaking would slow down important safety rules, defer or decrease benefits, and lead to the waste of resources on empty exercises that attempt to cast DOT consideration of safety improvements into the bill's risk assessment framework. Additional resources would clearly be required. It is not possible to quantify these resources at this time. The resources needed to comply with this mandate would either be diverted from the task of actually improving transportation safety, or would require new personnel and spending authority provided by Congress.

**QUESTION 5:** How does the Department obtain the information it uses to prepare risk assessments, cost-benefit analysis, or risk characterizations? Does the Department rely in part upon the private sector in providing the information needed by the Department to conduct such assessment or analyses? If so, would the Act require the Department to obtain additional information from the private sector in order to comply with the Act's requirements?

**RESPONSE:** As noted above, the Department typically does not perform risk assessments and characterizations of the kind cited in the bill. With respect to cost-benefit analyses, the Department often relies heavily on information provided by the private sector (including DOT information collection requirements) as well as safety audits, enforcement investigations, and accident investigations conducted by DOT and the National Transportation Safety Board. To the extent that DOT had to create risk assessments and risk characterizations, it is likely that we would need additional private sector information, since our current sources do not generate information that would lend itself to those kinds of documents.

**QUESTION 6:** Please identify the regulations expected to be proposed or promulgated in the next two years which would require a Regulatory Impact Analysis under Title VII, an analysis of risk reduction benefits and costs or a certification under Subtitle B of Section 3201, or a peer review under Section 3301. What additional procedures would the Department be required to follow to issue such regulations if the Act were enacted into law? Would the Act permit judicial review of agency actions beyond what is presently permitted under the Administrative Procedure Act? Please estimate the additional time and resources that would be necessary to complete the expected rulemaking following the required procedures. If the Department is subject to court-ordered

or statutory deadlines for completion of any such regulations, can the Department comply with the Act and still meet such deadlines?

RESPONSE: We have attached a copy of the most recent DOT listings in the Semi-Annual Regulatory Agenda. All the rules set forth in the Agenda would trigger the Title VII requirement for a regulatory impact analysis (RIA), since all DOT rules affect more than 100 persons. This represents a massive increase in time and resources over existing practice, since now only significant rules, as defined in Executive Order 12866, require an RIA. Since many DOT rules that affect 100 persons are not rules that have major economic or programmatic impacts, this requirement would generate much paper to little effect.

We have enclosed a list of rules that the Department has processed in the past two years that are significant under Executive Order criteria. It is likely that some of them would have an economic impact of \$100 million or more in any one year. A peer review under section 3301 would probably be required of these rules. Also, it is reasonable to assume that most of the DOT-designated significant rules on the Agenda (which include, but are not limited to, the rules on the list) would have annual costs of \$25,000,000 or more, and hence would be subject to the risk reduction benefits and costs analysis requirement of section 3201. Implementing these requirements would be very costly and time-consuming for the Department.

Like risk assessments themselves (which DOT would have to do to comply with the section 3201 requirement), peer reviews are not applicable to the bulk of DOT safety rules. Peer reviews may well be relevant to scientific estimates of the toxicity of an air pollutant, but they are irrelevant to an FAA determination that the airspace around an airport should be reconfigured or a Coast Guard rule that barge pilots should receive additional training in radar techniques. In addition, section 3201 (a)(3) and (5) appear to require safety rules to have several findings or certifications pertaining, by their own terms, only to health and environmental regulations. Finding ways of twisting the DOT rulemaking process into these inapplicable molds would clearly require new procedures as well as much time and effort that would be diverted from the business of improving safety.

We are not, at the present time, able to quantify the costs that these procedures would impose on the Department's budget. The more important point, however, is that the need to comply with these procedures would defer, and thus diminish, safety benefits to the public by delaying rules unnecessarily. For example, NHTSA estimates that a year's delay in implementing a new vehicle safety standard concerning head impacts in vehicle interiors would result in a loss of 1150-1400 lives over 20 years. The extra procedural requirements imposed by these provisions would take more than enough time to postpone such a NHTSA rule to the next model year, resulting in this loss.

The current version of H.R. 9 appears not to have language making noncompliance with its provisions specifically subject to judicial review. Nor, however, is there any disclaimer of reviewability for agencies' alleged noncompliance with the bill's requirements. Consequently, it is likely that these matters would be subject to litigation, with the substantial legal uncertainty involved sufficient to create needless confusion, delay, and blockage in the regulatory process. The Department is frequently subject to statutory deadlines for its rules. Addition of these requirements would make it even more difficult for the Department to meet statutory deadlines or otherwise respond in a reasonably timely manner.

QUESTION 7: Are the requirements of section 3105 for risk characterization (taking into account the definitions in 3106) consistent with the Department's understanding of sound scientific principles for risk assessment and risk characterization? Would the requirements of section 3105 preclude the Department from considering any information, models, or assumptions in assessing or characterizing risk? How would the Department be able to take into account risks to special subpopulations which may have higher susceptibility than "average"?

RESPONSE: Because this agency typically does not do risk assessments and characterizations in the way the bill assumes, we are not in the best position to assess the impact of these standards. On their face, the standards appear to include some degree of flexibility, but we would defer to the views of other agencies having greater expertise in matters of this kind.

QUESTION 8: To the extent not already addressed in previous answers, please identify all risk assessment documents, regulatory proposals or decisions, reports to Congress, or other documents made available to the public by the Department which include characterizations of risks that would be subject to the requirements of section 3105.

RESPONSE: In the short time available, we have not been able to assemble a group of documents meeting this request. Our assumption, as stated above, is that the Department has little material responsive to this request.

QUESTION 9: Please estimate the cost of complying with the peer review requirements of section 3301, taking into account the provisions of Title VII requiring Regulatory Impact Analyses. How would the Department implement the requirement for peer review of "economic assessments," "economic information," and "cost assessments"? Would the Department be precluded from issuing any regulation until the required peer review, peer review report, and response to the peer review, had been completed and made available to the public? How long would such a process be likely to take? Would such peer review panels be subject to the Federal Advisory Committee Act?

RESPONSE: It would be extremely difficult for the Department to comply with the peer review requirements of section 3301. First, for many DOT rulemakings, it is questionable whether there are significant numbers of "independent and external experts" to act as peer reviewers. On many issues, most expertise resides either in the regulated industry (e.g., the airlines) or the agency (e.g., the FAA). The former is not independent and the latter is not external. Second, because of the requirement that all economic information in risk reduction analyses under section 3201 be evaluated, DOT would have to conduct peer reviews of the analyses of a great many rulemakings. Finding peer reviewers, paying the reviewers (presumably they want reimbursement for their time, which would have to come out of DOT safety budgets), and delaying rulemakings under peer review (which we estimate would take several months to complete) would all add to the time, complexity, and cost of the rulemaking process.

While the text of Title III does not specify that agencies are precluded from issuing covered rules absent a peer review, the requirement to conduct peer reviews would be a matter of statute, with which agencies are obligated to comply. Given that the bill does not exclude compliance with its provisions from judicial review, the absence of peer review could form a basis for a court to invalidate a rulemaking that a party challenged under the Administrative Procedure Act.

It is not clear whether peer review panels would be subject to the Federal Advisory Committee Act (FACA). Generally speaking, FACA applies to situations in which an agency seeks consensus advice or recommendations from a group of persons from outside the agency. We do not know whether the information by a peer review panel would be considered advice or recommendations (as distinct from simply being the comments of outside experts); nor are we sure whether a peer review panel is tasked with coming to consensus concerning its comments to the agency.

MONDAY, FEBRUARY 26, 1979

PART II



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DEPARTMENT OF  
TRANSPORTATION  
Office of the Secretary

IMPROVING  
GOVERNMENT  
REGULATIONS

Regulatory Policies and Procedures

(MINOR CORRECTIONS MADE)

DISTRIBUTION: T-W-2; T-XYZ-2 (MINUS BASIC REQUIREMENTS)

11034

[4910-62-M]

## DEPARTMENT OF TRANSPORTATION

Office of the Secretary

(OST Docket No. 86)

## IMPROVING GOVERNMENT REGULATIONS

Regulatory Policies and Procedures

AGENCY: Department of Transportation.

ACTION: Adoption of Regulatory Policies and Procedures.

SUMMARY: The Department of Transportation establishes policies and procedures for simplification, analysis, and review of regulations. These policies and procedures are issued pursuant to Executive Order 12044 on "Improving Government Regulations." It is expected that these policies and procedures will result in fewer, simpler, more comprehensible and less burdensome regulations; improve the opportunity for effectiveness of public involvement; and generally increase the efficiency of the Department's regulatory programs by requiring periodic review of regulations to assure their continued need.

EFFECTIVE DATE: March 1, 1979.

FOR FURTHER INFORMATION CONTACT:

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## SUPPLEMENTARY INFORMATION:

## BACKGROUND

Improvement of government regulations has been a prime goal of the Carter Administration. There should be no more regulations than necessary, and those that are issued should be simpler, more comprehensible, and less burdensome. Regulations should not be issued without appropriate involvement of the public; once issued, they should be periodically reviewed and revised, as needed, to assure that they continue to meet the needs for which they originally were designed.

To further encourage and promote the many efforts to improve the Department's ("Department") regulations, on January 31, 1978, the Secretary of Transportation issued a statement of Policies and Procedures for Simplification, Analysis, and Review of Regulations published in the *Federal Register* on March 8, 1978 (43 FR 9582). These policies and procedures were the product of many months of work by all elements of the Department. They were issued initially as an internal memorandum, rather than as a formal Department Order, for two reasons: one, so that the Department might gain a working familiarity with them and make any required changes before issuing them as an Order, two, so that the Department might more easily make any changes required when the anticipated final Executive Order addressing these concerns was issued.

On March 23, 1978, the President issued a final Executive Order on this matter, "Improving Government Regulations" (E.O. 12044; 43 FR 12661, March 24, 1978). Section 5 of that Executive Order requires the following:

Each agency shall review its existing process for developing regulations and revise it as needed to comply with this Order. Within 60 days after the issuance of the Order, each agency shall prepare a draft report outlining: (1) a brief description of its process for developing regulations and the changes that have been made to comply with this Order; (2) its proposed criteria for defining significant agency regulations; (3) its proposed criteria for identifying which regulations require regulatory analysis; and (4) its proposed criteria for selecting existing regulations to be reviewed and the list of regulations that the agency will consider for its initial review. It shall be published in the *Federal Register* for public comment.

Based upon Executive Order 12044, and the Department's working experience with its internal procedures, appropriate modifications to the Department's Policies and Procedures for Simplification, Analysis, and Review of Regulations were made. As modified, those policies and procedures were published for public comment in the *Federal Register* on June 1, 1978 (43 FR 23925); the Department's list of regulations that it planned to consider for its initial review and the Department's first semi-annual Regulations Agenda of each proposed and each final regulation that the Department expects to publish in the *Federal Register* during the succeeding 12 months or such longer period as anticipated also appeared in the same *Federal Register*. (43 FR 23918 and 23884)

In response to the Department's publication of its Notice of Proposed Regulatory Policies and Procedures (proposal), a large number of public comments were received. To assist the public in reviewing the changes that have been made to the Department's proposal in response to these public comments, the following paragraph-by-paragraph analysis of the changes made has been provided.

## EXPLANATION OF CHANGES TO REGULATORY POLICIES AND PROCEDURES

## PARAGRAPH 1. PURPOSE

No comments directly relating to this paragraph were received and no changes have been made to the Department's proposal.

## PARAGRAPH 2. CANCELLATION

No comments directly relating to this paragraph were received and no changes have been made to the Department's proposal.

## PARAGRAPH 3. EFFECTIVE DATE

No public comments pertaining to this paragraph were received but an effective date of March 1, 1979, has been inserted in the blank.

## PARAGRAPH 4. REFERENCES

No public comments directly relating to this paragraph were received and no changes have been made to the Department's proposal.

## PARAGRAPH 5. COVERAGE

A number of commenters suggested that additional detail be added to the procedures to help determine when a regulation is significant. The different commenters provided a variety of criteria for inclusion in the proposal. The Department believes that its procedures for identifying significant regulations are working quite well. Moreover, it is noteworthy that the Department publishes as Agenda which includes all significant as well as non-significant regulations it is considering issuing over the next year or longer, as anticipated. Thus, the public can determine, for itself, how the procedures are being applied in practice. Additionally, many of the criteria suggested by the commenters already fit within the existing, general criteria contained in the Department's proposal. Still others addressed too specific a problem and, if included, could eventually result in an extremely lengthy list of items. However, where suggested additional criteria could be helpful, the Department has decided to incorporate them into its proposal. Some of the suggested language was changed because, as proposed, it could have included many nonsignificant regulations. The new criteria that the Department has added are contained in paragraphs 5a(2) (d) through (g).

One commenter was concerned about the use of the nearly identical terms "major" and "significant" to define regulations. The regulatory policies and procedures which were in effect in the Department at the time Executive Order 12044 was issued used the term "major". In the proposal, the term "major" was changed to "significant" to conform with the language in the Executive Order. This should have answered the commenter's concern.

One commenter suggested that the public should be provided an opportunity to comment on the determination that a regulation is or is not significant. The initial classification of significant or nonsignificant may be made a year or more before the issuance of the regulation.

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ence of the first regulatory document; however, if an agency knows that it is going to take action in an area, it must list the regulation, with its classification, in the Department's Regulations Agenda which is published in the *FEDERAL REGISTER*. The classification of the regulation can be changed at any time up to the issuance of the final rule. For example, generally, a non-significant regulation would be published as an ANPRM or NPRM in the *FEDERAL REGISTER*, with an opportunity for public comment. This public comment could lead to a reclassification of the item. For these reasons, it is the opinion of the Department that no change need be made to the proposal.

Several commenters stated that the definition of "emergency" regulation should be more carefully defined and limited. One of these commenters suggested that "emergency regulations should instead be issued in interim form with a self-executing nullification clause written into the rule." Another commenter suggested that "emergency" regulations should be subject to public comment, even after issuance. To ensure that emergency regulations are given full consideration in the Department and to avoid possible abuses, the Department's proposal required the completion of a Regulatory Analysis or Evaluation subsequent to the issuance of the otherwise significant emergency regulation, unless the Secretary grants an exception. The Department's proposal also suggested the solicitation of comments, through a formal notice, subsequent to the issuance of an emergency rule. Thus, if warranted, the rule could be changed. To further restrict discretion in this area would be unwise, especially within the Department of Transportation which is made up of agencies that basically have responsibility for safety regulation. Moreover, to issue all emergency regulations in an "interim form" would not be workable. For example, an emergency regulation might require the immediate purchase and installation of a replacement part. Once the installation is completed, withdrawing the "interim rule" would be of no value. Finally, there are other possible steps the public can take. For example, many of the initiating offices have procedures for petitions for rulemaking; the public can request a rule change by petition and the agency must respond to that petition. For these reasons, the Department has determined that no changes to the proposal are necessary.

One commenter asked for clarification on "the exclusion of regulations issued in accordance with forward rulemaking provisions of the Administrative Procedure Act." Apparently, by the word "forward", the commenter

was referring to "formal". The proposal stated that the procedures do not apply to "[r]egulations issued in accordance with the formal rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 556, 557)." This statement is taken directly from Executive Order 12044 (Sec. 6(b)(1)), which also does not apply to these sections. For these reasons, the Department has determined that no changes to the proposal are necessary.

Another commenter was concerned with rulemakings which are begun before the new procedures go into effect and suggested that a "freeze" be instituted on new rulemaking until the procedures are in effect. The Department already has in effect, since March 1, 1978, regulatory policies and procedures which are substantially similar to those that are contained in this document. When this is considered along with the fact that many Departmental regulatory proposals may either be required by statute or needed to correct a safety problem, a "freeze" would be unwarranted. The Department has determined, therefore, that no change to its proposal is necessary.

## PARAGRAPH 6. OBJECTIVES

Two commenters had suggestions that related to the paragraph on "necessity". One thought there was a lack of criteria for what would constitute a justifiable need for a regulation and the other suggested that a regulation should not be issued until it is demonstrated that it "is needed and will attain its objectives without unintended side effects." The Department believes that the concept of "necessity" within the framework of its regulatory responsibilities is not subject to any clearer, more workable definition. However, for clarity, a phrase has been added to paragraph 6e ("Reasonableness") to clearly indicate that anticipated side effects should be considered. It should also be noted that, under paragraph 9a(3), the "direct and indirect effects" of a regulation are considered in determining its significance.

One commenter suggested that, in addition to the objectives of simplification and public involvement, another "area of prime concern is the determination by an agency that legislative goals are being met by a regulation in the most effective way without unnecessary burden to the public" and that this criterion should be stressed during all stages of the development of a regulation. As a general objective, the Department's proposal already provides for this in paragraph 6e ("Reasonableness") and thus the Department believes that no change to the proposal is necessary.

Another commenter suggested that "once rules are in place, changes and reinterpretations of such rules should be severely limited." Any change to an existing regulation would be subject to the "necessity" standard of paragraph 6a. This should meet the concern of the commenter and the Department has determined that a change to the proposal is not necessary.

One commenter suggested that "a statement should be made to the effect that regulations should not be issued which are overlapping or duplicative of the regulations of either the initiating office or of another governmental agency regulating in the same area." Paragraph 6c ("Simplicity") already essentially sets forth this objective. Therefore, the Department has determined that a change to the proposal is not necessary.

## PARAGRAPH 7. DEPARTMENT REGULATIONS COUNCIL

A number of commenters suggested that the Regulations Council's meetings should be open to the public and/or that the minutes should be made available to the public. Two of the commenters suggested that the proceedings of the Department Regulations Council are subject to the Government in the Sunshine Act (5 U.S.C. 552b).

There is no legal requirement that Council meetings be open to the public. The Government in the Sunshine Act requires open meetings of agencies headed by more than one person. The Federal Advisory Committee Act, the other general "open meeting" statute, requires open meetings of advisory committees at least one of whose members is not a full-time federal official or employee. Neither of these statutes applies because the Regulations Council is not an agency and all of its members are full-time Federal officials.

In the opinion of the Department, the Council's usefulness to the Secretary depends upon the candor with which members express their views and that candor might well be inhibited were the meetings or minutes completely open and available. Secondly, many of the matters to be discussed by the Council will be in the preliminary and developmental stages, subject to considerable modification prior to any publication. Premature disclosure of some of these matters might tend to mislead the public as to the Department's position, as well as hinder implementation of the ultimate decision.

The creation of a Department Regulations Council goes beyond the requirements of Executive Order 12044. The Department believes that the Council will provide many benefits to the public, such as ensuring that a va-

riety of views and interests are represented when a matter is reviewed. The Department believes that, as proposed, this portion of the policies and procedures ensures the full effectiveness of the Council and no change is warranted.

A number of commenters also suggested that there should be a mechanism for the public to appeal matters to the Regulations Council. The Council's primary responsibility is to review matters within the Secretary's areas of responsibility and make recommendations to him or her. As part of this responsibility, the Regulations Council is actively involved in the review of significant regulations and the Regulations Agenda and in assuring compliance with the Regulatory Policies and Procedures. Thus, no special appeal to the Council is deemed necessary and the Department has determined that no change to its proposal should be made.

One commenter was concerned with a "lack of precision as to which matters are referred to the Council" and how those matters are handled when before the Council. The commenter requested rules of procedure and accountability. Since the Council is comprised of the top policymaking officials of the Department and is generally only providing advice or recommendations, not taking final action on any matter, discretion and informality appear to be better working tools than the detailed procedures suggested by the commenter. For that reason no change has been made to the proposal.

#### PARAGRAPH 8. RESPONSIBILITIES OF INITIATING OFFICES

Four commenters expressed concerns about the relationship between the Secretary and the head of the initiating office with respect to the authority to classify or issue a regulation. One was concerned that the Secretary might be taking away power vested in an Administrator; the other three stated that the Secretary should have more responsibility in this area. One commenter noted that the proposal required "only that the new regulation and work plan be reviewed and approved by the head of the initiating office before proceeding with further development" and felt that this was inconsistent with Executive Order 12044 which requires that such review must be by "the agency head." The head of the initiating office has the authority to formulate or issue regulations; therefore, the head of the initiating office has the authority to carry out the review steps required by Executive Order 12044. However, to enable the Secretary to carry out his or her responsibilities, the Departmental procedures provide for review and concurrence by the Secretary at

any time, including commenting on the development of issues, reviewing progress, and concurring in decisions. For example, at various stages, but especially during review of the Semi-annual Regulations Agenda and the bi-monthly updates of the Agenda, the Secretary plays a role in the classification of a regulation as "significant" or "nonsignificant". Additionally, for information purposes, the Work Plan is also submitted to the Office of the Secretary as soon as it is prepared. For these reasons, the Department has determined that changes to the proposal are not necessary.

One commenter was concerned with the accountability of decisionmaking officials. The Department believes that the increased responsibility for regulations given to the heads of the initiating offices by the proposal provides effective accountability and no change is deemed necessary.

#### PARAGRAPH 9. REVIEW OF SIGNIFICANT REGULATIONS

One commenter noted the lack of an explanation of how a proposal originally judged nonsignificant can be changed to significant (or vice versa) after public review. The Department agrees that this does warrant amplification and the proposal has been revised to include a new paragraph 91 which provides that, if the initiating office wishes to reclassify a significant regulation to nonsignificant, it shall so advise the Secretary in writing, and shall make the change only after receiving the Secretary's concurrence. This can be done at any time during the rulemaking process, if the initiating office determines the change is necessary. If a regulatory project is changed from nonsignificant to significant, the Secretary would be advised either through the Semi-annual Regulations Agenda, the bi-monthly updates to that Agenda, or through the submission of a regulatory document to the Secretary for concurrence. If the Secretary decides that a regulation should be reclassified as significant, under existing procedures the Secretary already has the authority to send a simple memorandum directing such a change.

Because regulations can be reclassified at any time under the procedures, the Department believes that it is important to keep the public advised at each stage of the regulatory process of the classification of a regulation. Therefore, the Department has decided to revise paragraph 9a to provide that if a regulation is considered nonsignificant it will now be accompanied by a statement in the FEDERAL REGISTER to that effect both at the time the regulation is proposed, as the proposal required, and when the final rule is published.

Two commenters suggested additional items for inclusion in the Work Plan. Some of the items requested were already included in the proposed requirements for a Work Plan. With respect to the others, it is the opinion of the Department that to further expand the Work Plan is unnecessary and might make the proposal unworkable. Therefore, no changes have been made to the proposal.

One commenter suggested that a Work Plan should be required for all non-emergency rulemaking proposals, not just significant ones. The Department believes that imposing such additional paperwork requirements on the initiating offices would not achieve benefits worth the additional burden. Therefore, the Department's proposal has not been changed.

One commenter was concerned that there was no provision in the Work Plan for an assessment of necessary technical expertise before the rulemaking begins. Such an assessment would generally be part of the consideration by the head of the initiating office of the major issues involved and the alternative approaches to be explored. For that reason, no change has been made to the proposal.

#### PARAGRAPH 10. REGULATORY ANALYSES AND EVALUATIONS

A number of commenters recommended that the Department expand and further define its criteria for requiring a Regulatory Analysis. One also suggested that when an agency is authorized to regulate in more than one area, such as safety and fuel economy, both areas of regulation should be taken into account. Another commenter suggested a more precise explanation of the methods used for the economic analyses. Finally, one of the commenters suggested that regulations should be issued only when it is demonstrated that the prospective benefits are not outweighed by the economic costs. On its own initiative, the Department has decided to add one new item to paragraph 10a to cover matters which have a substantial impact on the balance of trade. Because the Department requires either a Regulatory Analysis or an Evaluation, both of which include economic analyses, for all regulations the Department does not believe that the list of criteria need be expanded further. Although it is contemplated that an Evaluation usually would not be as extensive as Regulatory Analysis, some regulations not requiring a Regulatory Analysis might have an economic effect that would result in an extensive Evaluation. With respect to the concern about agencies that regulate in more than one area, this is covered by paragraph 6a ("Reasonableness"), which requires consideration of

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consequences. In response to the request for a more precise definition of the analytical methods to be used, it is the Department's opinion that the variety of regulatory actions handled within the Department requires a great deal of discretion in the choice of methodology. For example, there might be a great deal of difference between the methodology used to examine a Federal Aviation Administration regulation which affects air carriers and another which affects only the operators of small aircraft; this methodology may differ further from that necessary to analyze a National Highway Traffic Safety Administration regulation which affects all automobile operators. With respect to the comment on the cost/benefit ratio, the economic evaluation required for every regulation includes an assessment of the costs and benefits. In addition, the "Reasonableness" provision requires consideration of burdens. Therefore, the Department believes no change to its proposal is necessary.

One commenter suggested explaining fully to the public any decision not to require a Regulatory Analysis by providing a detailed estimate of how the proposed rule fell short of the criteria. As explained above, if a Regulatory Analysis is not done, an Evaluation must be prepared and placed in the public rulemaking docket. The economic analysis contained in the Evaluation would, by its very nature, provide a detailed estimate of where the proposed rule falls short of the Department's criteria for a Regulatory Analysis. Therefore, the Department believes no change to its proposal is necessary.

Two commenters suggested that a full and detailed Regulatory Analysis should be completed even before issuing an advance notice of proposed rulemaking. One purpose of an advance notice of proposed rulemaking is to encourage early public participation in the development of a rule. For this reason, an advance notice of proposed rulemaking often may simply identify a problem that has been raised and ask for comments and suggestions. It is noteworthy that Executive Order 12044 does not even require that a Regulatory Analysis be made available when an advance notice of proposed rulemaking is issued. The Department has gone beyond the Executive Order but recognizes that in many instances the economic analysis will be very preliminary and may primarily identify the questions that must be asked and the data that must be gathered. Because it wishes to encourage early public participation, the Department does not believe any change to its proposal would be appropriate.

One commenter suggested that the proposal be changed to require a state-

ment of how the public may obtain a copy of any draft Evaluation or final Regulatory Analysis or Evaluation. The Department's proposal simply required that the advance notice or notice of proposed rulemaking include "a statement of how the public may obtain a copy of the draft Regulatory Analysis for review and comment." The Department agrees that it would be advantageous to provide the suggested information; therefore, advance notices, notices of proposed rulemaking, and final rules will advise the public how they may obtain a copy of a draft or final Regulatory Analysis or Evaluation. Paragraph 10e and f of the proposal have been revised accordingly.

One commenter suggested a brief statement of the "cost/benefit relationship considered" in the development of a regulation" be released with a proposed rulemaking. Placing the draft Evaluation or Regulatory Analysis in the docket, and indicating in any advance notice or notice of proposed rulemaking how the public may obtain copies of it, appears to satisfy this request. For this reason, no change appears necessary to the Department's proposal.

#### PARAGRAPH 11. REVIEW AND REVISION OF EXISTING REGULATIONS

One commenter suggested that in reviewing existing regulations special consideration be given to the nature and extent of "complaints and/or suggestions received from users who implement your rules and regulations—states and local governments." The Department agrees that this emphasis can be added to the list of factors considered by the initiating office in identifying existing regulations for review. However, it should refer generally to "users" and not just to States and local governments. Paragraph 11b(1) has been amended accordingly.

On its own initiative, the Department has also expanded paragraph 11b(2) to stress the consideration, in determining the need for a review, that should be given to the number of requests for interpretation or the problems evidenced in enforcement.

Two commenters had suggestions concerning the scheduling of reviews. One commenter suggested establishing a schedule for review of each existing regulation on a regular pre-determined basis. The other commenter suggested establishing a definite period of time for the agency to complete a review. This commenter further suggested that if the review was not conducted during the set time, the regulation should be declared void until such time as the review is completed. Arbitrary schedules may mean delaying other, more important regulatory activity. Moreover, the Department be-

lieves that regulations, especially safety regulations, should not be declared void because some pre-determined schedule has not been met for what may be valid reasons. It must be stressed that, generally, the public does have the right to submit to the initiating office a petition for rulemaking if, in its opinion, changing technology or economic conditions or other factors support the need for a change in the regulations. For these reasons, the Department has decided to make no change to its proposal.

#### PARAGRAPH 12. OPPORTUNITY FOR PUBLIC PARTICIPATION

The Department recognizes the need for early and effective public participation. In light of that, as the following paragraphs indicate, a number of additions or changes have been made to paragraph 12. The Department wishes to stress, however, that other possible, additional methods of improving public participation are under consideration and may be added at a later date. The public will be given an appropriate opportunity to comment before they are added.

Several commenters suggested that the Department's procedures should provide for earlier and more meaningful public participation. A number of them suggested a variety of means to accomplish this. One commenter suggested making the draft of a notice of proposed rulemaking "available to those directly affected approximately 30 days in advance of its publication in the *FEDERAL REGISTER*." Much of what was requested by the commenters has already been provided to the maximum extent possible. For example, publication of the Work Plan or a summary of its major elements, as one commenter suggested, would defeat its purpose as a working tool. Much of the information in the Work Plan is published in the Agenda. However, to publish the rest of it at too early a stage could be misleading and could lead to premature public comment. It is the opinion of the Department that the public should be involved at the earliest stages, but that when a regulatory project has been sufficiently developed so that it can be discussed with the public, it should be discussed with all interested parties. The Department is also concerned that such steps as the circulation of draft notices of proposed rulemaking or the allowance of public participation in the development of a proposed regulation before any documents are even published in the *FEDERAL REGISTER* could violate either the Administrative Procedure Act (5 U.S.C. 551 et seq.) or the Federal Advisory Committee Act (5 U.S.C. App. 1). For these reasons the Department believes that a change should not be made to its proposal.

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One commenter felt Executive Order 12044 requires public comment before the issuance of a notice of proposed rulemaking. The Department believes that the Executive Order does not require this and that it is not necessary to change the Department's proposal. The Department does, however, wish to note that its procedures do provide for numerous, proper methods for obtaining public participation in the earliest stages in the development of a rule. For example, the Department encourages the appropriate use of advance notices of proposed rulemaking, advisory committees, regulatory conferences, and other general meetings with the public prior to the issuance of notices or advance notices.

Several commenters suggested that a longer comment period should be permitted on proposed regulations. However, requiring lengthy time periods may unnecessarily waste time. It appears better to allow the initiating offices discretion to determine, in appropriate instances, that a particular rulemaking should have a comment period longer than the minimum set forth in the proposal. Moreover, the initiating offices generally can grant a petition for an extension of time where warranted. The Department believes that the initiating offices have been quite liberal in both providing for comment periods well in excess of the minimums established in the procedures, as well as in granting petitions for extensions of time to comment. Therefore, the Department has determined that no changes should be made to its proposal.

Three organizations commented on the Department's proposal concerning State and local participation. Two comments in favor of more participation offered suggestions for increasing the opportunities for State and local government participation. Contrasted with this was a comment that these provisions create the possibility that the legal restraints placed on agency contacts during rulemaking can be flouted and undermine the Federal Advisory Committee Act. These commenters are addressing a portion of the Department's proposal taken directly from the two Presidential memoranda referenced in paragraph 4c. The concerns expressed are now being reviewed within the Executive Branch of the government. For that reason, the Department deems it improper at the present time to change the Department's proposal in this area.

One commenter suggested an expanded list of specific actions which could be required for public participation. Many of the suggestions were already contained in the Department's proposal; however, the Department has decided that some of the items not

already covered should be included, and paragraph 12a has been revised accordingly through the addition of paragraphs (3), (5) and (7).

Another commenter suggested that the nature and assumptions of the research relied on to support a particular regulatory approach be fully identified and its significance in the regulatory process acknowledged. The commenter further stated that any documentation should be clearly referenced and the source material made available for public review. The Department generally agrees with this commenter and, although it believes that the suggestions are being carried out within the Department, paragraph 12a has been revised by the addition of paragraph (6); this paragraph sets forth the need to (1) identify the nature and importance of the research and (2) place a copy of any source material in the public rulemaking docket.

One commenter suggested that critical research studies should be subject to peer review by persons with a demonstrated expertise in the area of the study. It is not clear at what stage or in what manner such peer review would be accomplished. The existence of such studies will be clearly noted in an advance notice or notice of proposed rulemaking in accordance with paragraph 12a(6); peer review could be accomplished during the review of these notices. Additionally, when copies of critical research studies relating to rulemaking are ready for release, they should be made available to the public in general and not just to a limited group of individuals or organizations. For that reason, the Department has decided to make no changes to its proposal.

Another commenter was concerned about the public's limited ability to rebut comments submitted to the docket and also noted the limited availability of the docket to people outside Washington, D.C. As part of its effort to increase public participation in its rulemaking, the Department is interested in adopting reasonable methods for making the docket more readily available to the public and has examined this problem. For example, at least one agency has provided for a rebuttal period after the close of the initial comment period. Additionally, many of the Department's public hearings on rulemakings (many of which are held outside Washington, D.C.) allow speakers to rebut other comments. The Department does not feel that the use of a rebuttal period should be a requirement for all rulemakings, but to indicate its support for this procedure when it is deemed appropriate, the Department has added a new paragraph (4) to paragraph 12a.

Still another commenter suggested that all non-emergency rulemaking proposals should begin with an advance notice, and public participation. This unnecessarily takes away agency discretion. Not only may there be no reason in many cases to go through the double steps of an advance notice and a notice of proposed rulemaking, but the flexibility of the current process allows supplemental notices of proposed rulemaking to be issued in the instances where the initial notice was insufficient. Therefore, the Department believes no change to its proposal is necessary.

One commenter suggested that an advance notice should be used only for the purpose of exploring a possible problem area to determine whether regulations are needed, and a notice of proposed rulemaking should be used only to explore alternative solutions once the need for regulatory action has been determined. In many instances an advance notice is used as suggested. There appears, however, no reason to limit its use. For example, there may be no question that a regulation is needed but the agency may not have a clear idea of how to proceed. In these instances an advance notice of proposed rulemaking could not be used under the commenter's suggestion. For these reasons, the Department has decided to make no changes to its proposal.

Another commenter was concerned that the Department's proposal did not require that all nonsignificant regulations be subject to notice and public comment. It is the Department's policy that notice and public comment should be provided to the maximum extent possible, if this could reasonably be expected to result in the receipt of useful information. Since this policy has been in effect in the Department, many more regulatory proposals have been subjected to public comment. It is the Department's opinion, however, that Executive Order 12044 does not require that all nonsignificant regulations be subject to notice and public comment. For example, the Department is currently preparing an amendment to its Time Act regulations. When originally issued, the regulations inadvertently referred to the border between North Dakota and Nebraska, thereby eliminating South Dakota from the "time map." Having noted the error, the Department is preparing an amendment to return the South Dakota-Nebraska border. There appears to be no reason to provide for notice and public comment on this matter as it could lead to no meaningful public comment; it would be a waste of time and money and it would not be in the public interest. For these reasons, the Depart-

ment has determined that no change is necessary to its proposal.

One commenter noted that the Department proposals suggested that the public be encouraged to comment subsequent to the issuance of a final rule in certain instances. The commenter felt that the Department's regulations (49 CFR 5.27) indicate that such comments need not be considered. Paragraph 12d was intended to provide an opportunity for the public to comment after the issuance of a final rule, when it is not possible to ask for comment prior to its issuance. It was the Department's intention that this request for comments would be done through a formal rulemaking document which would establish a specified comment period. To clarify this, the Department has revised its proposal through the addition of clarifying language in paragraph 12d. In addition, the Department has determined that additional language is necessary to make clear its general intent under paragraph 12d. The Department has also decided to add a sentence to this paragraph requiring that, when a determination is made that notice and an opportunity for comment cannot be provided, a statement of the reasons should be included with the regulation when it is published in the *FEDERAL REGISTER*.

Another commenter suggested that industry members usually do not know the results of studies conducted by or for the Department at the time they make presentations at hearings and suggested that additional hearings be scheduled after such studies are published. Existing agency procedures already permit this where appropriate. Therefore, a change to the proposal is unnecessary.

#### PARAGRAPH 13. REGULATIONS AGENDA

Two commenters had concerns about the Agenda. One suggested that listing the publication dates meant that the Department had already made up its mind to go ahead with rulemaking on that particular subject. The other commenter was concerned with references to the Federal-aid Highway Program Manual and other documents such as Operations Review Notices for FAA programs, and suggested that the Agenda include information on how to secure such items in a timely fashion. This commenter also suggested that the format for the Regulations Agenda appears more workable than the format for the Review List and suggested that, for the sake of clarity and uniformity, both have the same format.

The Agenda very carefully indicates that the listing of a date does not indicate that a decision has been made to issue a notice or final rule; rather, the date simply indicates to the public

that, if a decision is made to issue such a document, it can be expected by that date. However, to alleviate any problems, the Department has revised paragraph 13b (3) to change "publication date" to the "date for a decision on whether to issue the proposed or final regulation." Other language changes to conform with this have been made to paragraphs 13 a and b.

With respect to the concern stated by the other commenter about the references to documents that some members of the public do not have, these references were provided as extra information to assist those who do have such documents. Moreover, contact points for further information were provided. However, to further assist the public, the Department has revised its procedures to indicate how referenced documents can be obtained by adding a new requirement to paragraph 13b (2).

#### GENERAL

Two commenters suggested that, after the first year, an analysis of how the procedures are working be prepared and published. The Department recognizes that the promulgation of these policies and procedures is only the first step and that it is more important to assure that they are being effectively implemented. Therefore, the Department plans to make such an evaluation and will provide the public with an opportunity to make comments. The Department does not believe a change to its proposal is necessary to accomplish this.

The Department of Justice has recommended that: (1) "no proposed regulation be considered nonsignificant if it will have a disparate impact based on sex"; (2) "the 'Review and Revision of Existing Regulations' should include a paragraph specifically calling for an amendment of unnecessary or inappropriate gender-based terminology in existing regulations"; and (3) "compliance with E.O. (Executive Order) 12044 include a review of all proposed new regulations for unnecessary or inappropriate gender-based distinctions." The Department generally agrees with this policy and has already taken action on the matter. On December 12, 1977, the General Counsel advised the initiating offices of the Department to take appropriate action to phase sex-neutral terms into their regulations. As a general rule, they were advised that sex-neutral terms should be used whenever a new part of the *Federal Register* was drafted or a major revision to a part was undertaken. Also, they advised that in many situations sex-neutral terms could be used in minor revisions and still avoid inconsistencies with other portions of the regulations. It is the Department's position that, proceeding in this fashion,

it should be able to phase in sex-neutral terms in a relatively orderly manner. However, with respect to the Department of Justice's specific request, if a regulation would have a "disparate impact based on sex", it should fit within the definition already contained in the proposal for significant regulations. The other two recommendations seem unnecessary and inappropriate for inclusion in a general document such as the Department Regulatory Policies and Procedures. The Department wishes to stress, though, that it is taking steps to eliminate inappropriate gender-based terminology in existing regulations as well as in new regulations. Therefore, no further change to the proposal is deemed necessary.

One commenter suggested bi-monthly sessions be established as a forum for industry to give input to the Department on its regulations. Not enough information was given by the commenter to indicate how such hearings would be effective. Hearings are held by the Department to solicit suggestions on particular regulations or general areas of concern. General, bi-monthly sessions do not appear structured enough to lead to meaningful results. Therefore, the Department has made no change to its proposal.

One commenter noted that one of the Department's initiating offices has never published procedures in the Code of Federal Regulations governing the features of its regulatory process. Although this matter is technically outside the scope of the notice, the Department will review this matter and determine the feasibility of having all its initiating offices publish such procedures.

One commenter was concerned that one of the initiating offices of the Department presently has procedures whereby regulatory materials are issued by means of "notices" and "orders". Any matter which fits within the definition of regulation as used in the Administrative Procedure Act, Executive Order 12044, or the Department's Regulatory Policies and Procedures must conform to the requirements in those documents. No change to the proposal is necessary.

One commenter suggested that the Department's proposal fails to achieve the objective of rendering a rulemaking process "more efficient and predictable in the creation and delivery of agency policy." The Department believes that the process will be much more efficient and predictable through the use of such procedures as the Agenda, the Work Plans and public devices to encourage greater public participation. Therefore, the Department does not believe that changes are needed in its proposal.

One commenter suggested that in the final procedures "a function responsibility chart be included that could be used to follow the regulations through the various functions and departments of the agency during the development/review process." The Department does not feel it is necessary to amend its proposal to accomplish this objective but will give consideration to preparing such charts and publishing them in the *Federal Register* at a later date. Even if not published in the *Federal Register*, such charts could be used in conjunction with another recommendation, which the Department has adopted, to provide seminars around the country on use of the Department's regulatory processes.

One commenter expressed concern with the lack of provisions in the Departmental proposal to prohibit "retroactive rulemaking." It is not clear what the commenter means by "retroactive rulemaking." The only regulations which could be thought to be "retroactive" are rules which do not take effect until issued, but apply, for example, to any product manufactured or action taken after the date the notice was issued. This is generally intended to prevent defeat of the purpose of any final regulation by those who might take action in response to the proposed regulation. Not only is this not, technically, a retroactive rulemaking, but the public also has an opportunity to comment on the applicable date during the notice and comment stage. As a result, the Department does not deem it appropriate to revise its proposal.

One commenter suggested that the Department's procedures include a requirement for the development of a three- to five-year plan for significant regulatory activity relating to the safe transportation of hazardous goods. The National Highway Traffic Safety Administration has already published a five-year plan and another initiating office has one under consideration. Although others may consider it, due to the amount of effort necessary to prepare such a document and to the fact that the Department's current Regulations Agenda covers a full year or longer, the Department does not feel it appropriate to require initiating offices to prepare such a plan.

One commenter was "strongly opposed" to the "NEHTSA policy of funding self-appointed and proclaimed consumer advocates and representatives in their journeys to Washington, or wherever the concerned hearings might be taking place in order to voice their own comments as the opinion of the general public." This comment is generally outside the scope of the notice. However, the Department would like to explain how the National

Highway Traffic Safety Administration program works. Under the program regulations, members of the public are invited by notice in the *Federal Register* to apply for financial assistance. Funding is available to any individual or organization, both non-profit and profit-seeking, that can demonstrate that it is financially unable to participate effectively, and that its participation could contribute substantially to a full and fair determination of the issues involved in the proceeding.

In addition to the above, the Department would like to note that other minor, editorial changes have been made throughout the proposal.

Issued in Washington, D.C. on February 18, 1978.

BROCK ADAMS,  
Secretary of Transportation.

#### DEPARTMENT OF TRANSPORTATION

#### REGULATORY POLICIES AND PROCEDURES

##### 1. PURPOSE

This Order establishes objectives to be pursued in reviewing existing regulations and in issuing new regulations; prescribes procedures and assigns responsibilities to meet those objectives; and establishes a Department Regulations Council to assist and advise the Secretary in achieving those objectives and improving the quality of regulations and the policies and practices which affect the formulation of regulations.

##### 2. CANCELLATION

a. The following documents are superseded and cancelled:

(1) The Secretary's memorandum of March 23, 1976, on the subject of "Departmental Regulatory Reform."

(2) Notice 76-5 entitled "Policies to Improve Analysis and Review of Regulations" issued April 13, 1976, and published in the *Federal Register* on April 16, 1976 (41 FR 16200-01).

(3) The Secretary's memorandum of February 8, 1977, on the subject of "DOT Regulations."

(4) The Deputy Secretary's memorandum of March 9, 1977, on the subject of "Review of Regulations—Interim Regulations."

(5) The General Counsel's memorandum of April 25, 1977, on the subject of "Authorship of Regulatory Documents."

(6) Department of Transportation Order 2050.4 on the subject of "Procedures for Considering Inflationary Impacts."

(7) The Secretary's memorandum of January 31, 1978, and the statement attached thereto, on the subject of "Policies and Procedures for Simplification, Analysis, and Review of Regulations."

b. The controls listed in the table of "Controls of Certain Powers and Duties" in the DOT organization manual (DOT Order 1100.22A, Figure I-C) requiring the head of an operating administration to coordinate notices of proposed rulemaking and regulations with the Office of the Secretary before issuance are superseded and suspended pending their cancellation by amendment to the organization manual. The controls requiring the head of an operating administration to coordinate regulatory documents with another operating administration are not affected by this Order and continue to be the responsibility of the originating operating administration.

##### 3. EFFECTIVE DATE

This Order is effective March 1, 1978.

##### 4. REFERENCES

a. Title 5, United States Code, sections 552(a)(1) and 553 which prescribe general procedural requirements of law applicable to all Federal agencies regarding the formulation and issuance of regulations.

b. Executive Order 12044, "Improving Government Regulations," which prescribes general policy and procedural requirements applicable to all Federal executive agencies regarding the improvement of existing and future regulations.

c. Presidential memoranda of March 25, 1978, and February 25, 1977, for the heads of executive departments and agencies, which prescribe general policy and procedural requirements applicable to all Federal executive agencies regarding State and local government participation in the development and promulgation of significant Federal regulations having a major intergovernmental impact.

##### 5. COVERAGE

###### a. Definitions.

(1) *Initiating office* means an operating administration or other organizational element within the Department, the head of which is authorized by law or delegation to issue regulations or to formulate regulations for issuance by the Secretary.

(2) *Significant regulation* means a regulation that is not an emergency regulation and that in the judgment of the head of the initiating office, or the Secretary, or the Deputy Secretary:

(a) Requires a Regulatory Analysis under paragraph 10a of this Order or is otherwise costly;

(b) Concerns a matter on which there is substantial public interest or controversy;

(c) Has a major impact on another operating administration or other

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parts of the Department or another Federal agency;

(d) Has a substantial effect on State and local governments;

(e) Has a substantial impact on a major transportation safety problem;

(f) Initiates a substantial regulatory program or change in policy;

(g) Is substantially different from international requirements or standards; or

(h) Otherwise involves important Department policy.

(See paragraph 9a of this Order for factors to consider in applying this definition.)

(3) *Emergency regulation* means a regulation that:

(a) In the judgment of the head of the initiating office, circumstances require to be issued without notice and opportunity for public comment or made effective in less than 30 days after publication in the FEDERAL REGISTER; or

(b) Is governed by short-term statutory or judicial deadlines.

(4) *Nonsignificant regulation* means a regulation that in the judgment of the head of the initiating office is neither a significant nor an emergency regulation.

#### b. Applicability.

(1) This Order applies to all rules and regulations of the Department, including those which establish conditions for financial assistance.

(2) This Order does not apply to:

(a) Any rulemaking in which a notice of proposed rulemaking was issued before the effective date of this Order and which was still in progress on that date;

(b) Regulations issued in accordance with the formal rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 556, 557);

(c) Regulations issued with respect to a military or foreign affairs function of the United States;

(d) Matters related to agency management or personnel; or

(e) Regulations related to Federal Government procurement. \*

#### 6. OBJECTIVES

To simplify and improve the quality of regulations, it is the policy of the Department that the following objectives be pursued in issuing new regulations and continuing existing regulations:

a. *Necessity.* A regulation should not be issued or continue in effect unless it is based on a well-defined need to address a specific problem.

b. *Clarity.* A regulation and any supplemental material explaining it should be clear, precise, and understandable to all who may be affected by it.

c. *Simplicity.* A regulation should be as short and uncomplicated as possi-

ble; before issuance, it should be coordinated as required within the Department and between the Department and other Federal agencies to eliminate or minimize unnecessary duplication, inconsistency, and complexity; it should be issued only after compliance costs, paperwork and other burdens on the public are minimized.

d. *Timeliness.* A regulation should be issued in time to respond to the circumstances that require it and should be modified or cancelled as those circumstances change.

e. *Reasonableness.* A regulation should provide a feasible and effective means for producing the desired results; it should be developed giving adequate consideration to the alternatives, to anticipated safety, environmental, social, energy, economic, and legal consequences, and to anticipated indirect effects; it should not impose an unnecessary burden on the economy, on individuals, on public or private organizations, or on State and local governments.

f. *Fairness.* Generally, a regulation should be issued only after a reasonable and timely opportunity has been provided for all interested persons to comment on it.

#### 7. DEPARTMENT REGULATIONS COUNCIL

a. *Membership; Chair and Vice-Chair.* A Department Regulations Council is hereby established composed as follows:

##### Regular Members

- (1) The Deputy Secretary—Chair
- (2) General Counsel—Vice-Chair
- (3) Assistant Secretary for Policy and International Affairs
- (4) Assistant Secretary for Budget and Programs
- (5) Assistant Secretary for Administration
- (6) Assistant Secretary for Governmental Affairs
- (7) Director, Office of Public and Consumer Affairs
- (8) Director, Departmental Office of Civil Rights

##### Ex Officio Members

- (1) Commandant of the Coast Guard
- (2) Federal Aviation Administrator
- (3) Federal Highway Administrator
- (4) Federal Railroad Administrator
- (5) National Highway Traffic Safety Administrator
- (6) ~~Urban Mass Transportation Ad-~~  
Administrator FTA
- (7) Saint Lawrence Seaway Development Corporation Administrator
- (8) Research and Special Programs Administrator

##### b. Functions and responsibilities. The Council:

(1) Monitors initiating offices' programs for reviewing and revising their existing regulations and makes recom-

mendations to the heads of initiating offices and the Secretary when appropriate with regard to the conduct and effectiveness of those programs;

(2) Considers each significant regulation referred to it and makes such recommendations as the members consider appropriate regarding the advisability of the Secretary's concurring in its issuance;

(3) On its own initiative or upon request, reviews, discusses, and makes such recommendations to the Secretary as the members consider appropriate regarding Department regulatory policies and procedures; and

(4) In coordination with the initiating office(s) concerned, designates such task forces or requires the preparation of such reports, analyses, or options papers as it considers necessary for proper Council consideration of any regulatory matter or inquiry referred to or initiated by the Council.

c. *Staff support.* The General Counsel provides regular staff support to the Council and designates an Assistant General Counsel to be responsible for performing the functions assigned to the General Counsel's office. These include the coordination of the staffing, analysis, and review of items coming before the Council or on which the Council requires additional information; the convening and management of task forces designed to review and improve major categories of existing regulations; and such additional duties as the Council may specify.

d. *Meetings; attendance of members.* The Council meets on a regular bi-monthly basis. It also meets on special occasions, at the call of the Chair, either on his or her own initiative or at the request of the head of an initiating office. Attendance by ex officio members is optional. Any member who is unable to attend a meeting may be represented at the meeting only by the member's principal deputy or Chief Counsel. A member may be accompanied by supporting staff for purposes of briefing the Council or assisting the member with respect to an agenda item or a significant regulation scheduled for discussion.

e. *Agenda.* The General Counsel's office prepares an agenda for each meeting and distributes it to the members in advance of the meeting, together with any documents to be discussed at the meeting. When the agenda includes consideration of a significant regulation, the General Counsel's office makes such arrangements with the initiating office as may be appropriate for briefing the Council and responding to questions concerning the regulation.

f. *Minutes.* The General Counsel's office prepares summary minutes following each meeting and distributes them to the members.

### 8. RESPONSIBILITIES OF INITIATING OFFICES

a. The head of each initiating office is primarily responsible for:

(1) Reviewing proposed regulations to ensure that they meet the objectives set forth in paragraph 6 of this Order;

(2) Issuing regulations within the scope of his or her statutory or delegated authority;

(3) Coordinating proposed regulations with other Federal agencies and other operating administrations and organizational elements within the Department; and

(4) In conjunction with the Assistant Secretary for Governmental Affairs, consulting with State and local governments as required under the memoranda referenced in paragraph 4c of this Order in the development of regulations to be issued by that office.

b. To improve the quality of existing and future regulations in accordance with the purposes and policies set forth in this Order, the head of each initiating office:

(1) Establishes and carries out a program for reviewing and revoking or revising existing regulations in accordance with paragraph 11 of this Order;

(2) Includes in the public docket for each proposed regulation a draft Regulatory Analysis or Evaluation as required under paragraph 10 of this Order;

(3) Includes in the public docket for each final regulation a final Regulatory Analysis or Evaluation as required under paragraph 10 of this Order;

(4) Submits Regulations Reports to the Department Regulations Council in accordance with paragraph 13a of this Order;

(5) Submits for the Secretary's concurrence, before issuance, regulatory documents pertaining to significant regulations, together with such supporting documentation as may be required by paragraph 9 of this Order;

(6) Advises the Secretary by memorandum, before issuance if possible, of the circumstances requiring emergency issuance of an otherwise significant regulation;

(7) Names a Regulations Officer to coordinate the review of regulations and act as principal staff liaison with the Council; and

(8) Informs the Deputy Secretary or the General Counsel of any regulatory matter that should be reviewed by or coordinated with the Council.

### 9. REVIEW OF SIGNIFICANT REGULATIONS

a. In determining whether a regulation is significant, the following things, among others, are considered:

(1) The type and number of individuals, businesses, organizations, and State and local governments affected;

(2) The compliance and reporting requirements likely to be involved;

(3) Direct and indirect effects of the regulation including the effect on competition; and

(4) The relationship of the regulations to those of other programs and agencies.

Proposed and final regulations that are not considered significant under this Order are accompanied by a statement in the FEDERAL REGISTER to that effect.

b. Before an initiating office proceeds to develop a significant regulation, the head of the initiating office considers the need for the regulation, the major issues involved and the alternative approaches to be explored. If he or she determines that further action is warranted, the initiating office then prepares a Work Plan. The Work Plan states or describes:

(1) The need for the regulation;

(2) The objective(s) of the regulation;

(3) The legal authority for the regulation;

(4) The names of the individual or organizational unit primarily responsible for developing the regulation and of the accountable official;

(5) Whether a Regulatory Analysis is likely to be required and how and where it will be produced;

(6) The probable reporting requirements (direct or indirect) that may be involved;

(7) A tentative plan for how and when the Congress, interest groups, other agencies, and the general public will have opportunities to participate in the regulatory process; and

(8) The tentative target dates for completing each step in the development of the regulation.

If the Work Plan is approved by the head of the initiating office, the development of the significant regulation may proceed.

c. As soon as it is approved, the Work Plan is submitted to the General Counsel for his or her information.

d. Before issuing for publication in the FEDERAL REGISTER any regulatory document of substantive significance (e.g., advance notice of proposed rulemaking, notice of proposed rulemaking, notice of withdrawal, supplemental notice or final rule) or a notice of an exclusively procedural nature (e.g., extending time for comments or scheduling a public hearing) pertaining to a significant regulation, the initiating office submits it to the Secretary for concurrence.

e. To receive Secretarial concurrence for the issuance of any regulatory document of substantive significance pertaining to a significant regulation, the initiating office submits it to the General Counsel's office at least 30 days before the proposed date of issuance;

included with this submission is (1) an approved Work Plan, (2) a draft or final Regulatory Analysis or Evaluation, and (3) a summary of the results of any coordination outside the initiating office. Once a Work Plan and Regulatory Analysis or Evaluation is developed for a particular significant regulation, they are only updated and supplemented for successive regulatory documents pertaining to that significant regulation. In the case of a final rule submitted for Secretarial concurrence, there is an accompanying summary of meaningful public comments received.

f. Before submitting a final rule for Secretarial concurrence, the head of the initiating office reviews all the documents required to be submitted and determines that, at a minimum:

(1) The regulation is needed;

(2) The direct and indirect effects of the regulation have been adequately considered;

(3) Alternative approaches have been considered and the least burdensome of the acceptable alternatives has been chosen;

(4) Public comments have been considered and an adequate response has been prepared;

(5) The regulation is written in plain English and is understandable to those who must comply with it;

(6) An estimate has been made of the new reporting burdens or record-keeping requirements necessary for compliance with the regulation;

(7) The name, address and telephone number of a knowledgeable agency official is included in the publication; and

(8) A plan for evaluating the regulation after its issuance has been developed.

g. The General Counsel's office distributes each regulatory document and accompanying supporting documents received from an initiating office under paragraph 9d of this Order to all appropriate Secretarial Officers for review and coordinates their comments and recommendations for transmittal, together with a staff analysis, to the Secretary through the Deputy Secretary.

h. The Deputy Secretary or the General Counsel may refer a significant regulation to the Department Regulations Council for its consideration at its next regular or special meeting. This is done if, in the judgment of the Deputy Secretary or the General Counsel, the views of the Council on that regulation are desirable or likely to assist the Secretary in determining whether to concur in its issuance. Council consideration of a significant regulation is in addition to and not in lieu of Secretarial staff review; both are scheduled and coordinated so as to minimize delay in transmitting the re-

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sulting recommendations to the Secretary.

1. To receive Secretarial concurrence for the issuance of any notice of an exclusively procedural nature pertaining to a significant regulation, the initiating office submits a copy of the notice to the General Counsel's office at least 3 days before the intended date of issuance; included with this submission is a memorandum which specifies the intended date of issuance, states why the notice is required and describes any changes that it will cause in the previously anticipated schedule of action dates on the significant regulation concerned.

2. The General Counsel may concur for the Secretary in the issuance of a procedural regulatory document received from an initiating office under paragraph 9 of this Order, when warranted. The General Counsel advises the Secretary through the Deputy Secretary of such action as soon as possible. For all other such documents, the General Counsel's office advises the Secretary through the Deputy Secretary of each document received. Unless otherwise notified before the intended date of issuance, Secretarial concurrence may be presumed.

3. For an emergency regulation that otherwise would be significant, the initiating office includes with the regulation when published in the *FEDERAL REGISTER*, a statement of the reasons why it is impracticable or contrary to the public interest for the initiating office to follow the procedures of this Order and Executive Order 13044. Such a statement includes the name of the policy official responsible for this determination.

4. If, at any time during its development, the head of the initiating office determines that a regulation classified as significant should be reclassified as nonsignificant, he or she submits a memorandum providing the basis for the recommended change to nonsignificant to the Secretary for concurrence. The regulation continues to be handled as significant unless the Secretary concurs in the change.

#### 10. REGULATORY ANALYSES AND EVALUATIONS

a. Except as indicated in paragraph 10g of this Order, an initiating office prepares and places in the public docket a draft Regulatory Analysis for each of its proposed regulations that:

- (1) Will result in an annual effect on the economy of \$100 million or more;
- (2) Will result in a major effect on the general economy in terms of costs, consumer prices, or production;
- (3) Will result in a major increase in costs or prices for individual industries, levels of government, or geographic regions;

(4) Will have a substantial impact on the United States balance of trade; or

(5) The Secretary or head of the initiating office determines deserves such analysis.

b. Each draft Regulatory Analysis contains:

(1) A succinct statement of the problem and the issues that make the regulation significant;

(2) A description of the major alternative ways of dealing with the problem that were considered by the initiating office;

(3) An analysis of the economic and any other relevant consequences of each of these alternatives; and

(4) A detailed explanation of the reasons for choosing one alternative over the others.

c. A draft Regulatory Analysis addresses all salient points to the maximum extent possible. If data are lacking or there are questions about how to determine or analyze points of interest, the problem is noted in the draft Regulatory Analysis; to help elicit the necessary information during the public comment period on the advance notice or notice of proposed rulemaking, the appropriate questions are included in the advance notice or notice of proposed rulemaking.

d. The initiating office includes in each advance notice or notice of proposed rulemaking on a proposal requiring a Regulatory Analysis, an explanation of the regulatory approach being considered or proposed, a short description of the alternative approaches, and a statement of how the public may obtain a copy of the draft Regulatory Analysis for review and comment.

e. An initiating office prepares and places in the public docket for each of its proposed regulations not requiring a draft Regulatory Analysis, a draft Evaluation. This Evaluation includes an analysis of the economic consequences of the proposed regulation, quantifying, to the extent practicable, its estimated cost to the private sector, consumers, Federal, State and local governments, as well as its anticipated benefits and impacts. Judgment is exercised by the head of the initiating office so that resources and time devoted to the Evaluation reflect the importance of the proposal. The initiating office includes in each advance notice or notice of proposed rulemaking requiring an Evaluation a statement of how the public may obtain a copy of the draft Evaluation for review and comment. If the head of the initiating office determines that the expected impact is so minimal that the proposal does not warrant a full Evaluation, a statement to that effect and the basis for it is included in the proposed regulation; a separate statement is not placed in the public

docket. For a significant regulation, the Evaluation also includes a succinct statement of the issues which make the regulation significant and an analysis of any other relevant consequences.

f. The initiating office prepares a final Regulatory Analysis for each final regulation that meets the criteria of paragraph 10a of this Order, otherwise, a final Evaluation, in accordance with the requirements of paragraph 10e of this Order, is prepared. The Regulatory Analysis or the Evaluation is placed in the public docket at the time of or before issuing the final regulation and the regulation is accompanied by a statement of how the public may obtain a copy of the Regulatory Analysis or the Evaluation for review.

g. An emergency regulation that otherwise would be nonsignificant is excepted from the requirements for any Evaluation. For an emergency regulation that otherwise would be significant, the initiating office prepares and places in the public docket as soon as possible after issuance of the notice or final regulation a Regulatory Analysis or Evaluation, whichever is appropriate, unless an exception is granted by the Secretary.

#### 11. REVIEW AND REVISION OF EXISTING REGULATIONS

a. Each initiating office establishes a program for reviewing its existing regulations and revoking or revising those regulations that it determines are not achieving their intended purpose. This review follows the same procedural steps for the development of new regulations.

b. In identifying existing regulations for review and possible revocation or revision and in determining the order in which they are to be reviewed, an initiating office considers:

- (1) The nature and extent of complaints or suggestions (including petitions for rulemaking) received, especially ones received from those directly or indirectly affected by the regulations;
- (2) The need to simplify or clarify language; consideration should especially be given to the number of requests received for interpretations or the problems evidenced in the enforcement of the regulation;
- (3) The need to eliminate overlapping and duplicative regulations;
- (4) The need to eliminate conflicts and inconsistencies in its own regulations or those of other initiating offices or other agencies;
- (5) The length of time since the regulations were last reviewed or evaluated;
- (6) The importance and continued relevance of the problem the regulations were originally intended to solve;

(7) The burdens imposed on those directly or indirectly affected by the regulations;

(8) The degree to which technology, economic conditions or other factors have changed in the area affected by the regulation; and

(9) The number of requests received for exemption from a regulation and the number granted.

(c) Each initiating office prepares a list of the existing regulations it has selected for review and possible revocation or revision. It includes (1) a brief description of the reasons for each selection, (2) a target date for completing the review and determining the course of corrective action to be taken, and (3) the name and telephone number of a knowledgeable initiating office official who can provide additional information. The list of existing regulations selected is submitted to the Department Regulations Council through the General Counsel. It is updated as part of the initiating office's semi-annual Regulations Report and the bi-monthly supplements required under paragraph 13 of this Order. The semi-annual report includes any final action taken or determination made since the last list.

d. The General Counsel's office consolidates the initiating offices' lists of existing regulations selected for review for the Council and from that consolidation prepares a semi-annual list for publication in the *FEDERAL REGISTER* as part of the Department Regulations Agenda. *FEDERAL REGISTER* publication is for the stated purpose of sharing information with interested members of the public. Choosing to review a regulation does not indicate that it will be discarded or that it will not be enforced while under review.

#### 12. OPPORTUNITY FOR PUBLIC PARTICIPATION

a. Initiating offices should take appropriate steps, including the following, to increase the opportunity for public participation:

(1) In addition to publishing proposals and notices of regulatory actions in the *FEDERAL REGISTER*, an initiating office should, in appropriate circumstances, provide a clear, concise notice to publications likely to be read by those affected, and, to the extent practical, notify interested parties directly.

(2) If the subject is unusually complex, or if there is a considerable potential for adverse effects from a failure to provide an opportunity for early public participation, the initiating office should consider supplementing the minimum rulemaking steps required by section 553 of Title 5, United States Code. For example, an advance notice of proposed rulemaking may be employed to solicit comments and suggestions on an upcoming notice of pro-

posed rulemaking or an open conference may be held at which a discussion between all interested parties would help narrow or clarify issues. However, such supplementary procedures should be used only when they will serve to clarify the issues and enhance effective public participation. They should not be used if they would delay the process of developing the regulations unless significant additional information is to be gained by the initiating office or the public.

(3) When appropriate, an initiating office may solicit views through surveys or panels.

(4) When the issues involved warrant it and time permits, an initiating office should allow time for the public to submit rebuttal to comments submitted in response to proposals.

(5) To the extent permissible, an initiating office may consider providing financial assistance to persons who lack the resources to participate meaningfully in its regulatory proceedings.

(6) An initiating office should identify, in a statement accompanying a proposed or final regulation, the nature of the research relied on to support a particular regulatory approach; the statement should clearly indicate the importance of the research in the development of the regulation; and the source material should be made available for public review by placing a copy in the public docket.

(7) As necessary, the Department, and its initiating offices, provides information and instruction through public meetings and publications, in the use of its regulatory policies and procedures, especially with respect to public participation.

b. The public is provided at least 60 days to comment on proposed significant regulations. In the few instances where the initiating office determines this is not possible, the proposal is accompanied by a brief statement of the reasons for a shorter time period.

c. The public is generally provided at least 45 days to comment on proposed nonsignificant regulations. When at least 45 days are not provided, the proposal or the regulation is accompanied by a brief statement of the reasons.

d. To the maximum extent possible, notice and an opportunity to comment on regulations should be provided to the public, even when not required by statute, if such action could reasonably be anticipated to result in the receipt of useful information. When an initiating office does not provide notice and an opportunity for the public to comment, (1) a statement of the reasons is included with the final regulation when it is published in the *FEDERAL REGISTER* and (2) when reasonable, the initiating office should provide notice and opportunity to comment subsequent to the final regu-

lation. This action can be taken in conjunction with a plan for evaluating the regulation after its issuance.

e. If any of the national organizations representing general purpose State and local governments (including the National Governor's Association, the National Conference of State Legislatures, the Council of State Governments, the National League of Cities, the United States Conference of Mayors, the National Association of Counties, and the International City Management Association) notifies the department, including any of its initiating offices, that it believes a regulation included on the Department's Regulations Agenda would have major intergovernmental impact, the initiating office develops a specific plan, in conjunction with the Assistant Secretary for Governmental Affairs, for consultation with State and local governments in the development of that regulation. Such consultation includes the solicitation of comments from the above named groups, from other representative organizations and from individual State and local governments as appropriate.

In determining appropriate action, to help ensure the practicality and effectiveness of the programs, the initiating office considers the following:

(1) State and local sectors constitute the delivery mechanisms for most of the actual services the Federal Government provides;

(2) State and local sectors have concerns and expertise;

(3) Early participation by State and local officials in the planning process helps ensure broad-based support for the proposals that are eventually developed; and

(4) Early participation also ensures that priorities developed at the Federal level will work in conjunction with and not at cross-purposes to priorities at the State and local level.

Whenever a significant proposed regulation identified as having a major intergovernmental impact, is submitted to the Office of Management and Budget for review or is published in the *FEDERAL REGISTER*, it is accompanied by a brief description of (1) how State and local governments have been consulted, (2) what the nature of the State and local comments was and (3) how the agency dealt with such comments.

#### 13. DEPARTMENT REGULATIONS AGENDA

a. Each initiating office prepares a semi-annual Regulations Report summarizing each proposed and each final regulation that office is considering for issuance and publication in the *FEDERAL REGISTER* during the succeeding 12 months or such longer period as may be anticipated. This Report is submitted to the Department Regula-

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tions Council, through the General Counsel, not later than the last working days of June and December each year and supplemented with a bi-monthly updating report not later than the last working days of February, April, August, and October each year.

b. The Report specifies for each proposed and final regulation being considered for issuance and publication:

- (1) A title;
- (2) A description (including information on how any referenced document may be obtained);
- (3) The earliest expected date for a decision on whether to issue the proposed or final regulation;
- (4) The name and telephone number of a knowledgeable initiating office official who can provide additional information; and
- (5) Whether it is a significant or a nonsignificant regulation.

The Semi-Annual Regulations Report includes any final action taken since the last report.

c. For a significant regulation, the Report also briefly states:

- (1) Why it is considered significant;
- (2) The past and anticipated chronology of the development of the regulation;
- (3) The need for the regulation;
- (4) The legal basis for the action being taken; and
- (5) Whether a Regulatory Analysis is required.

d. For non-significant regulations issued routinely and frequently as part of an established body of technical requirements (such as the Federal Aviation Administration's Airspace Rules) to keep those requirements operationally current, the Report only states:

- (1) The general category of the regulations;
- (2) The identity of a contact office or official; and
- (3) An indication of the expected volume of issuance; individual regulations are not listed.

e. The General Counsel's office consolidates the initiating offices' Regulations Reports for the Council and from that consolidation prepares a semi-annual Department Regulations Agenda for publication in the FEDERAL REGISTER. FEDERAL REGISTER publication is for the stated purpose of sharing with interested members of the public the Department's preliminary expectations regarding its future regulatory actions and does not impose any binding obligation on the Department or initiating offices with regard to any specific item in the Agenda or preclude regulatory action on any unspecified item.

[FR Doc. 79-5573 Filed 2-23-79; 8:45 am]

NQ CODE 4910-59-M

The Department's experience since March 1, 1978, indicates that a great deal of time is required to prepare and review the bi-monthly updates. That experience also indicates that the bi-monthly updates are not necessary for the effective management of the Department's rulemaking program. In this connection, our efforts to keep the semi-annual Agendas as current as possible while they are undergoing review by the DOT Regulations Council have resulted in very little additional information having to be added to the next bi-monthly update. Also, under our new Regulations Policies and Procedures, the rulemaking initiating offices are required to prepare a Work Plan for each significant regulation before the development of that regulation may proceed. As soon as

the Work Plan is approved by the head of the initiating office, it is sent to the Department's General Counsel, who can then circulate it to members of the Regulatory Council, if necessary, for their information. This enables appropriate offices outside the rulemaking initiating office to be advised at a very early stage of proposals concerning significant regulations, thereby reducing the need for bi-monthly update reports.

For the above reasons, the Department believes that the present requirement in its Regulatory Policies and Procedures for two updating reports between each semi-annual Agenda should be changed to require only one updating report. This amendment accomplishes that change. Some of the resulting time that will be saved can then be spent in further improving the quality of the semi-annual Agendas which are published in the Federal Register.

As discussed above, the bi-monthly update reports have not been published and were intended for internal purposes. As such, they relate to a matter of agency management. Because of this and the nature of the change being made by this amendment, public notice and an opportunity for comment is not required. There is, however, an immediate need to relieve Department offices of an unnecessary burden. This amendment is, therefore, being adopted without first inviting public comment and it is being made effective upon issuance.

Issued in Washington, D.C. on May 9, 1979.

Frank Adams,  
Secretary of Transportation

#### The Amendment

In consideration of the foregoing, the Department of Transportation amends the second sentence of paragraph 13a. of the department's Regulatory Policies and Procedures to read as follows:

The Report is submitted to the Department Regulations Council, through the General Counsel, not later than the last working days of June and December each year and supplemented with an updating report not later than the last working days of March and September each year.

(R2 Doclet No. 58; Asmt; No. 1)

FR Doc. 79-14826 Filed 5-11-79 8:43 am

BILLING CODE 4910-62-01

#### DEPARTMENT OF THE TREASURY

##### Privacy Act of 1974; Revised System of Records

Agency: Office of the Secretary,  
Department of Treasury.

#### ACTION: Revised System of Records.

**SUMMARY:** Pursuant to the requirements of the Privacy Act of 1974 (5 U.S.C. 552a) the Chief, Library Division, gives notice of the proposed revised system of records retitled, Document Delivery Control System (Treasury/OS 00.194). The original system, Library Circulation Control Records (Treasury/OS 00.194), has been expanded to include data required for the distribution of current news publications and the name of the system is therefore amended to reflect its expanded scope. The new data will provide information needed to improve distribution procedures and to control costs. A revised system report was filed with the Office of Management and Budget, the Speaker of the House and the President of the Senate.

**DATES:** Comments must be received not later than June 13, 1979. This proposed system will become effective on July 14, 1979, unless prior notice is given by this Department prior to that time.

**ADDRESS:** Department of the Treasury, Office of Administrative Programs, Library Division, Room 5030 Main Treasury Building, 1500 Pennsylvania Avenue, N.W., Washington, D.C. 20220.

**FOR FURTHER INFORMATION CONTACT:** Anne E. Stewart, Chief, Library Division, Department of the Treasury, Room 5030, Main Treasury Building, 1500 Pennsylvania Avenue, N.W., Washington, D.C. 20220, 202-566-2069. Dated: May 3, 1979.

W. J. McDonald,

Acting Assistant Secretary (Administration).

Treasury/OS 00.194

#### SYSTEM NAME:

Document Delivery Control System

#### SYSTEM LOCATION:

Department of the Treasury, Office of Administrative Programs, Library Division, Room 5030, Main Treasury Building, 1500 Pennsylvania Avenue, N.W., Washington, D.C. 20220.

#### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Department employees who are library users.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

Employees who borrow library materials or receive current news publications or library material on distribution.

#### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301

#### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The information is used by the Library staff to locate materials withdrawn from

the Library collection, to distribute library periodicals and current news publications, to conduct surveys of continuing user needs, and to complete pre-exit clearance procedures for employees leaving the Department. For additional routine uses see Appendix AA.

#### POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

**STORAGE:**  
Records of publications borrowed from the Library are maintained in a computer disc file or in a card file. The computer files are maintained by name of the subscribers and by office locator information, room number and office billing location. The card file is maintained in the name of the individual borrower and title of publications.

#### RETRIEVABILITY:

Computer files are maintained by both individual name and office locator information, such as room number and billing location, and title of publication. The card file is maintained by individual name only.

#### RETENTION AND DISPOSAL:

Only current data is maintained in the computer and card files. Hard copy of the computer data is kept for one year. One year is defined as the current fiscal year and one fiscal year back.

(FR Doc. 79-14826 Filed 5-11-79; 8:43 am)

BILLING CODE 4910-25-01

#### VETERANS ADMINISTRATION

##### Basic Science Addition; VAMC, Huntington, W. Va. Finding of No Significant Impact

The proposed project provides for the construction of a Basic Science Addition at the Veterans Administration Medical Center, Huntington, West Virginia. The project proposes construction of a single building addition to be attached to the east side of Building No. 12. The building will contain facilities for the training of medical students from Marshall University School of Medicine.

The building site is presently a parking lot. As part of the described project, the displaced parking spaces will be provided for with additional parking added to the parking lots in the athletic field area. An existing station water tower will be relocated from the building site to the athletic field parking lot area.

The project will have definite impacts on the human and natural environment as they affect topography, surface runoff, erosion and the sanitary sewer

## DOT

USCG - Marine Safety Council, 2100 2nd Street SW, Room 3406, Washington, DC 20593. Working Hours: 8:00-3:00 (Monday-Friday).

FAA - Rules Docket (AGC 10), Office of Chief Counsel, Regulations and Enforcement Division, 800 Independence Avenue SW, Room 915C, Washington, DC 20591. Working Hours: 8:30-5:00.

FTWA - Docket Room, 400 7th Street SW, Room 4232, Washington, DC 20590. Working Hours: 8:30-3:30

FRA - Docket Clerk, 400 7th Street SW, Room 8201, Washington, DC 20590. Working Hours: 8:30-5:00

NHTSA - Docket Room, 400 7th Street SW, Room 5109, Washington, DC 20590. Working Hours: 9:30-4:00.

FTA - Docket Clerk, 400 7th Street SW, Room 9316, Washington, DC 20590. Working Hours: 8:30-5:00.

SLSDC - 400 7th Street SW, Room 5424, Washington, DC 20590. Working Hours: 8:15-4:45

RSPA - Docket Branch, 400 7th Street SW, Room 8421, Washington, DC 20590. Working Hours: 8:30-5:00

MARAD - Docket Clerk, 400 7th Street SW, Room 7300, Washington, DC 20590. Working Hours: 8:30-5:00.

OST - Docket Clerk, 400 7th Street SW, Room 4107, Washington, DC 20590. Working Hours: 9:00-5:30.

## Office of the Secretary—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
2519	Direct Flights .....	2105-AA73
2520	Price Advertising .....	2105-AB25
2521	Implementation of Amendments to the Equal Access to Justice Act .....	2105-AB73

## Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
2522	+Commercial Space Transportation: Financial Responsibility Requirements for Licensed Launch Activities .....	2105-AA26
2523	+Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments ..	2105-AB46
2524	+Proposed Policy on Peak Period Pricing of Airport Landing Fees .....	2105-AB63
2525	+Procedures for Transportation Workplace Drug-Testing Programs .....	2105-AB71
2526	+Passenger Manifest Information .....	2105-AB78
2527	+Licensing Commercial Space Launch Activities (Reg Plan Seq. No. 116) .....	2105-AB85
2528	+Accessibility of Passenger Vessels to Individuals With Disabilities .....	2105-AB87
2529	+Transportation for Individuals With Disabilities (Reg Plan Seq. No. 117) .....	2105-AC00
2530	+Limit of Liability for Desperate Ports .....	2105-AC01
2531	+Transportation for Individuals With Disabilities .....	2105-AC13
2532	Special Event Tours .....	2105-AC03
2533	Domestic Baggage Liability .....	2105-AC07
2534	Exemption from Property Tariff Filing Requirements .....	2105-AC08
2535	Disclosure of Code-Sharing Arrangements .....	2105-AC10
2536	Use of Direct Final Rulemaking .....	2105-AC11
2537	Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments ..	2105-AC12
2538	Dissection of Aircraft .....	2105-AC14
2539	Testimony of Employees of the Department and Production of Records in Legal Proceedings .....	2105-AC15
2540	Disclosure of Change-of-Gauge Services .....	2105-AC17

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.  
 + DOT-designated significant regulation.

## Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
2541	+Statement of Enforcement Policy on Rebating .....	2105-AB38
2542	+Price Advertising .....	2105-AB50
2543	+New Restrictions on Lobbying .....	2105-AB57
2544	+Nondiscrimination on the Basis of Handicap in Air Travel (Air Carrier Access Act) .....	2105-AB80
2545	+Nondiscrimination on the Basis of Handicap in Air Travel (Air Carrier Access Act) .....	2105-AB61
2546	+Nondiscrimination on the Basis of Handicap in Federally Assisted Programs and in Air Travel (Air Carrier Access Act) (Reg Plan Seq. No. 118) .....	2105-AB62
2547	+Aviation Charter Rules .....	2105-AB91

## DOT

## Office of the Secretary—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
2548	+Disadvantaged Business Enterprise (DBE) Regulation; General Update	2105-AB92
2549	+Random Drug-Testing Program	2105-AB94
2550	+Procedures for Transportation Workplace Drug- and Alcohol-Testing Programs	2105-AB95
2551	+Participation by Disadvantaged Business Enterprises in Airport Concessions	2105-AB99
2552	+Transportation for Individuals With Disabilities	2105-AC08
2553	Nondiscrimination on the Basis of Age in DOT Financial Assistance Programs	2105-AA09
2554	Direct Air Carrier Responsibility for Returning Stranded Charter Passengers	2105-AA40
2555	Air Travelers: Age Discrimination	2105-AA46
2556	Policy Statement on Airline Preemption	2105-AA46
2557	Diversion of Flights Within a Metropolitan Area	2105-AA78
2558	Simplified Aviation Exemption Procedures	2105-AA82
2559	Baggage Liability Notices in International Air Transportation	2105-AA84
2560	Simplified Airline Counter-Sign Notices	2105-AA86
2561	Smoking Aboard Aircraft	2105-AB58
2562	Centralization of Formal Hearing Dockets (OST)	2105-AB69
2563	Rules of Conduct in DOT Proceedings	2105-AB89
2564	Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations	2105-AC02
2566	Privacy Act Exemptions	2105-AC05

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.

+ DOT-designated significant regulation.

## Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identifier Number
2556	+Americans With Disabilities Act Accessibility Guidelines; Detectable Warnings	2105-AC08
2567	Transportation Acquisition Regulations	2105-AB54
2568	Transportation Acquisition Regulations; Rewrite	2105-AB75

+ DOT-designated significant regulation

## U.S. Coast Guard—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
2569	+Facility Response Plans for Hazardous Substances (94-048) (Reg Plan Seq. No. 119)	2115-AE87
2570	+Tank Vessel Response Plans for Hazardous Substances (94-032) (Reg Plan Seq. No. 120)	2115-AE88
2571	Regulated Navigation Area: Oliver Lock and Dam; Black Warrior River—MM 338	2115-AE79

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.

+ DOT-designated significant regulation

## U.S. Coast Guard—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
2572	+Structural and Operational Measures To Reduce Oil Spills From Existing Tank Vessels Without Double Hulls (91-045) (Reg Plan Seq. No. 121)	2115-AE01
2573	+User Fees for Approvals of Equipment, Laboratories, and Servicing Facilities (92-013)	2115-AE18
2574	+Federal Agency Access to the Oil Spill Liability Trust Fund (CGD 92-074)	2115-AE34
2575	+Great Lakes Pilotage (93-019)	2115-AE52
2576	+Escort Vessels in Certain U.S. Waters (91-202a)	2115-AE56
2577	+Establishment of Lightening Zones (93-081)	2115-AE90
2578	Training in the Use of Automatic Radar Plotting Aids (ARPA) (85-083)	2115-AB99
2579	Domestic Load Lines (86-013)	2115-AC37

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## U.S. Coast Guard—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
2580	Revision to Inflatable Liferaft Approval SOLAS 74/83 (85-205) .....	2115-AC51
2581	Regattas and Marine Parades (CGD 87-087) .....	2115-AC84
2582	Anchorage Regulations (86-079) .....	2115-AC96
2583	Controlling the Marine Asbestos Hazard (88-103) .....	2115-AC16
2584	General Revisions to Stability Regulations (Subchapter S) (89-038) .....	2115-AC34
2585	Tank Level or Pressure Monitoring Devices (CGD 90-071) .....	2115-AD69
2586	Criminal Record Reviews and Access to the National Driver Register (91-212) .....	2115-AD93
2587	Suspension and Revocation of Licenses, Certificates of Registry, and Merchant Mariners' Documents (91-213) .....	2115-AD94
2588	Manning Standards for Foreign Tank Vessels (91-215) .....	2115-AD87
2589	Reporting Marine Casualties (91-216) .....	2115-AD88
2590	Damage Stability Standards for Double-Hulled Tank Vessels (91-206) .....	2115-AE11
2591	State Access to the Oil Spill Liability Trust Fund (92-014) .....	2115-AE19
2592	Handling of Explosives or Other Dangerous Cargoes Within or Contiguous to Waterfront Facilities (92-026) .....	2115-AE22
2593	Lifboats, Rescue Boats, and Associated Equipment and Materials (93-021) .....	2115-AE40
2594	Prince William Sound Automated Dependent Surveillance System Incorporation by Reference (93-022) .....	2115-AE41
2595	Inspection and Certification Standards for OSRVs (93-031) .....	2115-AE43
2596	Inspection of Great Lakes Barges (93-017) .....	2115-AE49
2597	Certification of Seamen (92-042) .....	2115-AE53
2598	Approval of Inflatable Personal Flotation Devices (PFDs) for Recreational Boaters (93-055) .....	2115-AE58
2599	Facilities Transferring Oil and Hazardous Material in Bulk (93-056) .....	2115-AE59
2600	Stability Criteria for Bulk Grain Vessels (93-059) .....	2115-AE60
2601	Shipboard Fumigation (93-061) .....	2115-AE61
2602	International Load Lines (86-013a) .....	2115-AE70
2603	Revision of Damage Stability Requirements for New Passenger Ship Designs (94-010) .....	2115-AE75
2604	Aleutian Trade Act (94-025) .....	2115-AE77
2605	Inland Waterways Navigation Regulations, Wrangell Narrows, AK (94-026) .....	2115-AE78
2606	Vessel Rebuild Determinations (94-040) .....	2115-AE85
2607	Navigation Safety Equipment for Towing Vessels (94-020) .....	2115-AE91

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.

♦ DOT-designated significant regulation.

## U.S. Coast Guard—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
2608	+Offshore Supply Vessel Regulations (82-004 and 86-074) .....	2115-AA77
2609	+Licensing of Pilots—Manning of Vessels (84-060) .....	2115-AB67
2610	+Lifesaving Equipment—Implementation of 1983 Amendments to SOLAS 1974 (84-069) .....	2115-AB72
2611	+Small Passenger Vessel Inspection and Certification (CGD 85-080) .....	2115-AC22
2612	+Implementation of the Commercial Fishing Industry Vessel Safety Act (88-079) .....	2115-AD12
2613	+Double Hull Standards for Vessels Carrying Oil in Bulk (CGD 90-051) .....	2115-AD61
2614	+Discharge-Removal Equipment for Vessels Carrying Oil (CGD 90-068) .....	2115-AD66
2615	+Security for Passenger Vessels and Passenger Terminals (91-012) .....	2115-AD75
2616	+Financial Responsibility for Water Pollution (Vessels) (CGD 91-005) .....	2115-AD76
2617	+Direct User Fees for Inspection or Examination of U.S. and Foreign Commercial Vessels (91-030) .....	2115-AD78
2618	+Tank Vessel Response Plans (91-034) .....	2115-AD81
2619	+Facility Response Plans (91-036) .....	2115-AD82
2620	+Overfill Devices (CGD 90-071a) .....	2115-AD87
2621	+Drug Testing of Individuals Applying for Issuance or Renewal of Licenses, Certificates of Registry, or Merchant Mariners' Documents (91-223) .....	2115-AE29
2622	+Great Lakes Pilotage Rate Methodology (92-072) .....	2115-AE45
2623	Tankermen (79-116) .....	2115-AA03
2624	Fixed Fire-Extinguishing Systems on Uninspected Vessels (74-284) .....	2115-AA08
2625	Hybrid Personal Flotation Devices: Establishment of Approval Requirements (78-174) .....	2115-AA29
2626	Safety Standards for New Self-Propelled Vessels Carrying Bulk Liquefied Gases (82-058) .....	2115-AA95
2627	Safety/Security Zone Regulations .....	2115-AA97
2628	Anchorage Area Regulations .....	2115-AA98
2629	Fire Protection Regulations (CGD 83-026) .....	2115-AB36

## DOT

## U.S. Coast Guard—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
2630	Incorporation of Amendments to the International Convention for Safety of Life at Sea, 1974 (83-043)	2115-AR41
2631	Emergency Position Indicating Radio Beacons (EPIRBs) and Visual Distress Signals for Uninspected Vessels (87-016)	2115-AC09
2632	Carriage of Bulk Solid Materials Requiring Special Handling (87-089)	2115-AD02
2633	Requirements for Marine Terminals Transferring Bulk Liquefied Hazardous Gases (86-048)	2115-AD08
2634	Permits for the Transportation of Municipal and Commercial Wastes (89-014)	2115-AD05
2635	Vessel Identification System (89-050)	2115-AD06
2636	Regulated Navigation Area; Puget Sound, Washington (13-90-03)	2115-A708
2637	Claims Procedures Under the Oil Pollution Act of 1990 (CGD 91-035)	2115-A790
2638	Regulated Navigation Area: Puget Sound and Strait of Juan de Fuca, WA; Grays Harbor, WA; Columbia River and Willamette River, OR; Yaquina Bay, OR; Umpqua River, OR; Coos Bay, OR (13-90-28)	2115-A790
2639	Alteration of Obstructive Bridges (91-063)	2115-AE08
2640	Federal Pilotage Requirement for Foreign Trade Vessels (92-061)	2115-AE15
2641	New York Vessel Traffic Service (CGD 92-062)	2115-AE28
2642	Amendments to Hull Identification Number Regulations and New Requirements for Certificates of Origin (CGD 92-065)	2115-AE36
2643	Implementation of Regulation 25 of Annex 1 of MARPOL 73-78 Relating to the Development of Shipboard Oil Pollution Emergency Plans (93-030)	2115-AE37
2644	Regatta Regulations	2115-AE44
2645	Drawbridge Regulations	2115-AE46
2646	Simplified Process for Pollution Violation Cases (93-079)	2115-AE47
2647	Inland Navigation Rules; Lighting Provisions (94-011)	2115-AE66
2648	Amendment to 46 CFR 14: Revise Recordkeeping of Shipping Articles and Certificates of Discharge (94-004)	2115-AE71
2649	Regulations for the Control of Ballast Water Discharges From Ships in the Hudson River (94-005)	2115-AE72
2650	Regulated Navigation Area; Mississippi River, Miles 66 to 240 Above Head of Passes (08-94-006)	2115-AE76
2651	Notice of Hazardous Conditions (94-027)	2115-AE81
2652	Regulated Navigation Areas	2115-AE82
2653	Immediate Reporting of Casualties (94-030)	2115-AE84
2654	Radar Observer Endorsement for Operators of Uninspected Towing Vessels (94-041)	2115-AE88

† DOT-designated significant regulation.

## U.S. Coast Guard—Completed Actions

Sequence Number	Title	Regulation Identifier Number
2655	+Escort Vessels for Certain Tankers (91-202)	2115-AE10
2656	Traffic Separation Schemes and Shipping Safety Fairways off the Coast of California (83-032)	2115-AB29
2657	Posting Requirements on Inspected Vessels (87-031)	2115-JC08
2658	Written Warnings by Coast Guard Law Enforcement Officers (88-074)	2115-AD13
2659	Chesapeake Bay Traffic Separation Scheme (90-039)	2115-AD43
2660	National Vessel Traffic Service (VTS) Regulations (90-020)	2115-AD56
2661	New Terms of Validity for Certificates of Registry and Merchant Mariners' Documents (91-211)	2115-AD82
2662	Unnecessary Drawbridge Opening (91-059)	2115-AE14
2663	Refuse Recordkeeping for Ships (92-071)	2115-AE17
2664	Classifying, Packaging, and Communicating About Explosives (92-050)	2115-AE27
2665	Recreational Vessel Fee Amendments (92-066)	2115-AE32
2666	Bulk Hazardous Materials (92-100) and Noxious Liquid Substances List (92-100a)	2115-AE35
2667	Authorization for NTSB Officials To Be Allowed in the Pilot House or on the Navigation Bridge of Merchant Vessels While Underway (CGD 91-023)	2115-AE38
2668	Proof of Commitment To Employ Aboard U.S. Merchant Vessels (93-051)	2115-AE54
2669	Bridge-to-Bridge Radiotelephone Regulations; Inland Navigation Regulation (93-072)	2115-AE66
2670	Expansion of Safety Zone at Louisiana Offshore Oil Port (93-080)	2115-AE69
2671	Upgrades to the Bulk Hazardous Materials Tables (94-900)	2115-AE73
2672	Upgrades to the Noxious Liquid Substances List (94-901)	2115-AE74
2673	Regulated Navigation Area; Providence River, Providence, RI (01-93-030)	2115-AE80
2674	Documentation of Vessels (94-008)	2115-AE83

† DOT-designated significant regulation.

## DOT

## Federal Aviation Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
2675	Sightseeing Operations	2120-AF07

## Federal Aviation Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
2676	+Fuel System Vent Fire Protection	2120-AA49
2677	+Revision of Medical Standards and Certification Procedures	2120-AA70
2678	+Repair Station and Repairmen Certification Rules	2120-AC38
2679	+Air Carrier Training Programs	2120-AC79
2680	+Sole Radio Navigation System; Minimum Standards for Certification	2120-AD26
2681	+Fatigue Test Requirements for Aging Aircraft	2120-AD43
2682	+Revision of Part 108, Airplane Operator Security	2120-AD45
2683	+Revision of Part 107, Airport Security	2120-AD46
2684	+Alternative Means of Compliance	2120-AD66
2685	+Child Restraint Systems	2120-AD90
2686	+Reduced Altitude Separation	2120-AE51
2687	+Airport Land Use Compatibility Planning—Proposed Revisions	2120-AE64
2688	+Pilot, Flight Instructor, Ground Instructor, and Pilot School Certification Rules	2120-AE71
2689	+Anti-Drug and Alcohol Misuse Prevention Programs for Employees of Foreign Air Carriers Engaged in Specified Aviation Activities	2120-AE79
2690	+Mode S Transponder Requirement for Part 135 Operators	2120-AE81
2691	+Civil Penalty Assessment Procedures	2120-AE84
2692	+Corrosion Control Program (Reg Plan Seq. No. 122)	2120-AE92
2693	+Advanced Qualification Program	2120-AF00
2694	+Revised Access to Type III Exits	2120-AF01
2695	+Revision of Emergency Evacuation Demonstration Procedures to Improve Participant Safety	2120-AF21
2696	+Suspension of Certain Aircraft Operations From the Transponder With Automatic Pressure Altitude Reporting Capability Requirement	2120-AF30
2697	+Operations of Jet Aircraft in Commuter Slots at LaGuardia Airport and John F. Kennedy International Airport	2120-AF31
2698	+Procedures for Complaints Involving Federally Assisted Airports	2120-AF43
2699	+Overflights of Units of the National Park System	2120-AF46
2700	Composite Propellers	2120-AB05
2701	Review of Part 47, Aircraft Registration, and Part 49, Recording of Aircraft Titles and Security Documents	2120-AC17
2702	Installation of Crashworthy Fuselage Fuel Tanks and Fuel Lines	2120-AC87
2703	Maintenance Recordkeeping Requirements	2120-AD25
2704	High Intensity Radiated Fields Protection Standards for Aircraft Electrical and Electronic Systems	2120-AD32
2705	1-G Stalling Speed as a Basis for Compliance With Part 25 of the Federal Aviation Regulations	2120-AD40
2706	Cost of Services and Transfer of Fees to Part 187 from Parts 47, 49, 61, 63, 65, and 143	2120-AD91
2707	Visual Descent Points	2120-AE34
2708	Access Into the Cockpit	2120-AE35
2709	Airport Runway Incursion	2120-AE38
2710	Non-Federal Navigation Facilities	2120-AE54
2711	Persons Authorized To Perform Maintenance, Preventive Maintenance, Rebuilding, and Alterations	2120-AE57
2712	JAR/FAR Harmonization Initiatives—Systems and Equipment	2120-AE59
2713	JAR/FAR Harmonization Initiatives—Propulsion	2120-AE60
2714	JAR/FAR Harmonization Initiatives—Flight	2120-AE61
2715	JAR/FAR Harmonization Initiatives—Airframe	2120-AE62
2716	Part 71 Review: Airspace Designations	2120-AE65
2717	Stage 2 Airplane Operations in Hawaii	2120-AE83
2718	State Block Grant Program	2120-AE90
2719	Nashville, TN, Class B Airspace	2120-AE93
2720	Niagara Falls	2120-AE95
2721	Cincinnati, OH, Class B Airspace	2120-AE97
2722	Flight Attendant English Language Proficiency	2120-AE98
2723	Flight Operational Quality Assurance Program	2120-AF04
2724	Simulator Instructor—Medical Certificates	2120-AF08

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## Federal Aviation Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
2725	Changes in Type Design of Helicopters .....	2120-AF10
2726	Los Angeles, CA, Class B Airspace .....	2120-AF16
2727	Orlando, FL, Class B Airspace .....	2120-AF17
2728	Tampa, FL, Class B Airspace .....	2120-AF18
2729	Minimum Altitudes for the Use of an Air Pilot .....	2120-AF19
2730	Raleigh/Durham, NC, Class B Airspace .....	2120-AF20
2731	Revision of Certification Requirements: Mechanics and Repairman .....	2120-AF22
2732	Aviation Insurance .....	2120-AF23
2733	Revised Discrete Gust Load Design Requirement; Transport Category Airplanes .....	2120-AF27
2734	Advanced Simulation Plan Revisions .....	2120-AF29
2735	Future Harmonized Rotorcraft Rulemaking; Normal Category Maximum Weight .....	2120-AF33
2736	Emergency Medical Kits: Protective Glove Requirement .....	2120-AF37
2737	Powerplant Instruments: Fuel Pressure Indication .....	2120-AF41
2738	Sensitive Security Information .....	2120-AF49

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.  
 \* DOT-designated significant regulation.

## Federal Aviation Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
2739	*Aircraft Flight Simulator Use in Pilot Training, Testing, and Checking and at Training Centers (Reg Plan Seq. No. 123) .....	2120-AA83
2740	*Improved Standards for Determining Rejected Takeoff and Landing Performance .....	2120-AA87
2741	*Elimination of Airport Delays .....	2120-AA82
2742	*Passenger-Carrying and Cargo Air Operations for Compensation or Hire .....	2120-AC06
2743	*Flight Attendant Requirements .....	2120-AC32
2744	*Type and Number of Passenger Emergency Exits Required in Transport Category Airplanes .....	2120-AC43
2745	*Improved Survival Equipment for Inadvertent Water Landings .....	2120-AC72
2746	*Retrofit of Improved Seats in Air Carrier Transport Category Airplanes .....	2120-AC84
2747	*Drug Enforcement Assistance .....	2120-AD16
2748	*Airworthiness Standards; Occupant Protection Standards for Commuter Category Airplanes .....	2120-AD27
2749	*Fatigue Evaluation of Structure .....	2120-AD42
2750	*Crew Paining Requirements .....	2120-A088
2751	*Unescorted Access Privilege (Reg Plan Seq. No. 124) .....	2120-AE14
2752	*Aging Aircraft Safety (Reg Plan Seq. No. 125) .....	2120-AE42
2753	*Aircraft Ground Deicing and Anti-Icing Program .....	2120-AE70
2754	*Training and Checking in Ground Icing Conditions .....	2120-AF09
2755	*Traffic Alert and Collision Avoidance System (TCAS 1) .....	2120-AF24
2756	Objects Affecting Navigable Airspace .....	2120-AA09
2757	Miscellaneous Amendments .....	2120-AA50
2758	Airworthiness Standards, Crash Resistant Fuel Systems .....	2120-AA57
2759	Part 95 Instrument Flight Rules .....	2120-AA63
2760	Airworthiness Directives .....	2120-AA64
2761	Standard Instrument Approach Procedures .....	2120-AA65
2762	Airspace Actions .....	2120-AA66
2763	Standards for Approval for High Altitude Operation of Subsonic Transport Airplanes .....	2120-AB18
2764	Airworthiness Standards, Transport Category Rotorcraft Performance .....	2120-AB36
2765	Low Fuel Quantity Alerting System .....	2120-AB46
2766	Aircraft Engines: Fuel and Induction Systems .....	2120-AB76
2767	Airworthiness Standards; Turbohaft Engine Rotor Burst Protection .....	2120-AB91
2768	Airworthiness Standards: Aircraft Engines; Proposal for New One-Engine-Inoperative Ratings, Definitions, and Type Certification Standards .....	2120-AD21
2769	Improved Flammability Standards for Materials Used in the Interiors of Transport Category Airplane Cabins .....	2120-AD28
2770	Airplane Engine Cowling Retention .....	2120-AD34
2771	Allowable Carbon Dioxide Concentration in Transport Category Airplane Cabins .....	2120-AD47
2772	Centralization of Formal Hearing Dockets (FAA) .....	2120-AD63
2773	Protective Breathing Equipment; Cargo-Only Airplanes .....	2120-AD74

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## Federal Aviation Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
2774	Type Certificates for Some Surplus Aircraft of the Armed Forces .....	2120-AE41
2775	Amend Part 34 Fuel Venting and Exhaust Emission Requirements for Turbine Engine Powered Airplanes .....	2120-AE55
2776	Communication Systems: Removal of Fee Provisions .....	2120-AE68
2777	Fees for Certification Services Performed Outside the United States .....	2120-AE72
2778	Accelerated Stalls in Commuter Category Airplanes .....	2120-AE86
2779	Manned Free Balloons .....	2120-AE87
2780	Occupant Protection in Normal and Transport Category Rotorcraft .....	2120-AE88
2781	Holiday Give-Back Slots .....	2120-AE94
2782	Charlotte, NC, Class B Airspace .....	2120-AF02
2783	Extend: 3 Overwater Operations With a Single High-Frequency Communication System (HF) and a Single Long-Range Navigation System (LRNS) .....	2120-AF12
2784	Revision of Certain Flight Airworthiness Standards to Harmonize with European Airworthiness Standards for Transport Category Airplanes .....	2120-AF25
2785	Recent Flight Experience - Pilot in Command .....	2120-AF32
2786	Notification to ATC of Deviations from ATC Clearance and Instructions in Response to Traffic Alert and Collision Avoidance System Resolution Advisories .....	2120-AF35
2787	Streamlined Enforcement Process Test Program .....	2120-AF36

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.

♦ DOT-designated significant regulation.

## Federal Aviation Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
2788	♦ Civil Supersonic Aircraft Noise Type Certification Standards and Operating Rules .....	2120-AC22
2789	♦ Emergency Locator Transmitters .....	2120-AD19
2790	♦ Temporary Flight Restrictions .....	2120-AD55
2791	♦ Relief From Transponder-On Requirement for Aircraft With Limited Electrical Systems .....	2120-AE67
2792	♦ Anti-Drug Program for Personnel Engaged in Specified Aviation Activities .....	2120-AE82
2793	♦ Flight Attendant Duty Period Limitations and Rest Requirements .....	2120-AE91
2794	♦ Extension of Compliance Date for Installation of Digital Flight Data Recorders on Stage 2 Airplanes .....	2120-AF34
2795	♦ Prohibition Against Flights Within the Territory and Airspace of Afghanistan .....	2120-AF38
2796	♦ Prohibition Against Flights Within the Territory and Airspace of Yemen .....	2120-AF39
2797	♦ Prohibition Against Certain Flights Between the United States and Haiti .....	2120-AF40
2798	Airworthiness Standards; New Rotorcraft 30-Second/2-Minute One-Engine-Inoperative Power Ratings .....	2120-AB90
2799	Airworthiness Standards; Crash Resistant Fuel Systems in Normal and Transport Category Rotorcraft .....	2120-AC68
2800	Electrical and Electronic Systems Lightning Protection .....	2120-AC81
2801	Airworthiness Standards; Emergency Exit Provisions for Normal, Utility, Acrobatic, and Commuter Category Airplanes .....	2120-AD33
2802	Design Standards for Airplane Jacking and Tie-Down Provisions .....	2120-AD38
2803	Temporary Restriction of Instrument Approaches and Certain Visual Flight Rules Operations in High Pressure Weather Conditions .....	2120-AD75
2804	Model Rocket Operations .....	2120-AD84
2805	Exit Seating for On-Demand Operations .....	2120-AE44
2806	Part 145 Review: Repair Stations .....	<del>2120-AE58</del>
2807	♦ Renewal of Flight Instructor Certificates .....	2120-AF13
2808	Medical Standards (Final Rule; Emergency Amendment) .....	2120-AF42
2809	Review of Part 169 - Expenditure of Federal Funds for Nonmilitary Airports or Air Navigation Facilities Thereon .....	2120-AF44
2810	Offshore Airspace Reconfiguration; Valparaiso, FL, Terminal Area .....	2120-AF45
2811	Review of Part 47 - Aircraft Registration .....	2120-AF50
2812	Review of Part 49 - Recording of Aircraft Titles and Security Documents .....	2120-AF51

♦ DOT-designated significant regulation

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## Federal Highway Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
2813	*Commercial Driver Physical Fitness as Part of the CDL Process .....	2125-AD20
2814	*Qualification of Drivers; Epilepsy .....	2125-AD34
2815	Acquisition of Real Property for Rights-of-Way .....	2125-AC17
2816	Value Engineering .....	2125-AD33

+ DOT-designated significant regulation.

## Federal Highway Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
2817	*Commercial Driver's License Standards; Biometric Identifier .....	2125-AQ24
2818	*Weight Threshold Adjustments for Commercial Motor Vehicles .....	2125-AC27
2819	*Federal Motor Carrier Safety Regulations; General; Motor Vehicle Marking .....	2125-AC28
2820	*Qualification of Drivers; Vision .....	2125-AC82
2821	*Federal Motor Carrier Safety Regulations; General Transportation of Hazardous Materials .....	2125-AC78
2822	*Training for All Entry-Level Drivers of Commercial Vehicles .....	2125-AD05
2823	*Qualifications of Drivers; Hearing Deficiencies .....	2125-AD22
2824	*Department of Transportation (FHWA, FTA, and FRA) Environmental Impact and Related Procedures .....	2125-AD32
2825	Equal Employment Opportunity on Federal and Federal-Aid Construction Contracts (Including Supportive Services); Report Requirements .....	2125-AB15
2826	Truck Length and Width Exclusive Devices .....	2125-AC30
2827	Amendments to the Periodic Inspection Requirements .....	2125-AC47
2828	Commercial Driver Instruction Permits .....	2125-AC54
2829	Certification of Size and Weight Enforcement .....	2125-AC60
2830	Revision of Medical Examination Form and Procedures .....	2125-AC83
2831	Parts and Accessories Necessary for Safe Operation: Intermodal Cargo Containers .....	2125-AC74
2832	Longer Combination Vehicles—Driver Training .....	2125-AC92
2833	Highway Beautification .....	2125-AD24
2834	Parts and Accessories Necessary for Safe Operation: Sleeper Berths on Motor Coaches .....	2125-AD25
2835	Parts and Accessories Necessary for Safe Operation: Lighting Devices, Reflectors, and Electrical Equipment .....	2125-AD27
2836	Parts and Accessories Necessary for Safe Operation: Automatic Brake Adjusters and Brake Adjustment Indicators .....	2125-AD37
2837	Design Standards for Highways; A Policy on Geometric Design of Highways and Streets; Design and Construction Criteria .....	2125-AD38

+ DOT-designated significant regulation.

## Federal Highway Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
2838	*Qualification of Drivers; Diabetes .....	2125-AB91
2839	*Safety Fitness Procedures; Safety Ratings .....	2125-AC71
2840	*Transportation of Hazardous Materials; Highway Routing .....	2125-AC80
2841	*Management and Monitoring Systems .....	2125-AC97
2842	*Controlled Substances and Alcohol Use and Testing; Foreign-Based Motor Carriers and Drivers .....	2125-AD11
2843	*Federal Motor Carrier Safety Regulations; General; Intermodal Transportation .....	2125-AD14
2844	Centralization of Formal Hearing Dockets (FHWA) .....	2125-AC59
2845	Transportation of Hazardous Materials; Preemption Determination .....	2125-AD00
2846	Administration of Engineering and Design-Related Service Contracts; Private Sector Involvement Program .....	2125-AD03
2847	Removal of Obsolete and Redundant Regulations and Appendices .....	2125-AD28
2848	Motor Carrier Safety Assistance Program (MCSAP) Allocation Formula .....	2125-AD30
2849	Utility Relocations, Adjustments, and Reimbursement .....	2125-AD31
2850	Quality Assurance Procedures for Construction .....	2125-AD35
2851	Traffic Surveillance and Control; Technical Amendment .....	2125-AD36

+ DOT-designated significant regulation.

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## Federal Highway Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
2872	*State Compliance With CUL Program	2125-AD83
2853	Parts and Accessories Necessary for Safe Operation, Front Wheel Brakes on Mexican Commercial Motor Vehicles	2125-AD49
2854	Truck Size and Weight Restrictions on Longer Combination Vehicles and Vehicles With Two or More Cargo Carrying Units	2125-AD86
2855	Violations of Out-of-Service Orders—CDL Disqualifications	2125-AD99
2856	Erosion and Sediment Control on Highway Construction Projects	2125-AD09
2857	Removal of Obsolete and Redundant Right-of-Way Requirements	2125-AD01
2858	Forest Highway Portion of Public Lands Highway Program	2125-AD13
2859	Parts and Accessories Necessary for Safe Operation, Warning Devices for Stopped Vehicles	2125-AD17
2860	Parts and Accessories Necessary for Safe Operation, Protection Against Shifting or Falling Cargo	2125-AD18
2861	State Planning and Research Program Administration	2125-AD01
2862	Design Standards for Highways, Interim Selected Metric Values for Geometric Design, Design and Construction Criteria	2125-AD23
2863	Truck Size and Weight, National Network	2125-AD06

\* DOT-designated significant regulation.

## National Highway Traffic Safety Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
2864	*Review Passenger Car Front Seat Occupant Protection (Federal Motor Vehicle Safety Standard No. 208)	2127-AD82
2865	Review: Lamps, Reflective Devices, and Associated Equipment	2127-AB76
2866	Brake Lining	2127-AC66
2867	Standard 105: Hydraulic Brake	2127-AC94
2868	Review: Glass-Plastic Windshields	2127-AD29
2869	Rulemaking To Delete "Due Care" Provisions From the Occupant Crash Protection Standard	2127-AD54
2870	Brake Hoses and Fluids	2127-AD70
2871	Radiator Safety Cap	2127-AE59
2872	Lateral Performance Requirements for Fuel System Integrity	2127-AE83
2873	Accelerometer Mounting Arrangements	2127-AE84
2874	Review: Passenger-Car Back Seat Occupant Protection	2127-AE95
2875	Materials Used in Tires	2127-AF22
2876	Compressed Natural Gas (CNG)	2127-AF29
2877	Upgrade Performance Requirements	2127-AF36
2878	Test Device Placement	2127-AF40

\* DOT-designated significant regulation.

## National Highway Traffic Safety Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
2879	*Extend Antilock Brake System to Passenger Cars (Reg Plan Seq. No. 126)	2127-AE47
2880	*Light Truck Average Fuel Economy Standards for MYs 1996 Through 2006 (Reg Plan Seq. No. 127)	2127-AF16
2881	*Manual Cutoff Switches for Air Bags	2127-AF30
2882	Procedures for Considering Environmental Impacts	2127-AB79
2883	Seating Systems Performance	2127-AD08
2884	Standardized Display of Certification Labels	2127-AE71
2885	Uniform Guidelines for State Highway Safety Programs	2127-AE90
2886	Passenger Motor Vehicle Theft Data for Model Year (MY) 1992	2127-AE92
2887	Insurer Reporting Requirements for October 1994	2127-AE94
2888	Redefine Replaceable Bulb Headlamps	2127-AF00
2889	Tires on New Trailers	2127-AF05
2890	Compressed Natural Gas (CNG) Fuel Containers	2127-AF14
2891	Uniform Tire Quality Grading	2127-AF17
2892	Equivalent Measurements for Gaseous Fuels	2127-AF18
2893	Fractional Balance Headlamp Aim	2127-AF24

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## National Highway Traffic Safety Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
2894	Rigid Plastics in Windows .....	2127-AP28
2895	Improved Back Door Latch .....	2127-AF35
2896	Driving Range Determination for Dual Fuel Electric Passenger Automobiles .....	2127-AF37
2897	Driving Range for Dual Energy and Natural Gas Dual Energy Passenger Automobiles .....	2127-AF38
2898	Increase Femur Flexion Motion of the Hybrid III Test Dummy .....	2127-AF41
2899	Electric Vehicle Safety .....	2127-AF43
2900	Insurance Cost Information Regulation .....	2127-AF44

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.

+ DOT-designated significant regulation.

## National Highway Traffic Safety Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
2901	+Heavy Duty Vehicle Brake Systems (Formerly Truck and Trailer Brake Systems) .....	2127-AA00
2902	+Crashworthiness Ratings .....	2127-AA03
2903	+Truck Rear Underride Protection .....	2127-AA43
2904	+Flammability of Interior Materials - School Buses .....	2127-AA44
2905	+Reduce Head Injuries Due to Contact With Upper Vehicle Interior (Reg Plan Seq. No. 125) .....	2127-AB85
2906	+Lighting Simplification—Potential Amendments on Long-Term Issues .....	2127-AB87
2907	+School Bus Body Joint Strength .....	2127-AC19
2908	+Roll-over Protection .....	2127-AC64
2909	+Film Transmittance of Glazing Materials .....	2127-AC85
2910	+Wheelchair Lifts .....	2127-AD60
2911	+Dynamic Testing of Light Trucks and Vans for Side Impact .....	2127-AE49
2912	+Highway Safety Programs, Determination of Effectiveness .....	2127-AE89
2913	Proposed New Standard 135; Passenger-Car Brake System .....	2127-AA13
2914	Fuel Spillage .....	2127-AC82
2915	Incentive Grant Criteria for Drunk-Driving-Prevention Programs (Section 410) .....	2127-AD01
2916	Air Brake Systems, Stopping-Distance Performance .....	2127-AD07
2917	Issuance, Amendment, and Revocation of Rules: Procedural Regulations .....	2127-AD78
2918	Enforcement of the National Traffic and Motor Vehicle Safety Act .....	2127-AD83
2919	Stopping Distance Performance Requirements .....	2127-AE21
2920	Seat Adjustment Position .....	2127-AE22
2921	Emergency Exit Requirements for Non-School Buses .....	2127-AE25
2922	Certification Requirements of Multistage Vehicles .....	2127-AE27
2923	Optical Coatings and Heat Degradations .....	2127-AE38
2924	Vehicles Equipped With Long-Stroke Brake Chambers .....	2127-AE54
2925	Referee Material .....	2127-AE58
2926	Consumer Information Regulation - Vehicle Stopping Distance .....	2127-AE61
2927	Bus Window Emergency Exit .....	2127-AE62
2928	Antilock Warning Signals .....	2127-AE75
2929	Define Major Component Parts of a Vehicle .....	2127-AE85
2930	Define Designated Seating Position .....	2127-AE96
2931	Miniature and Nonfilament Light Sources .....	2127-AE97
2932	Test Procedures for Transmission and Key Locking Requirements .....	2127-AE99
2933	Air-Over-Hydraulic Brake System .....	2127-AF01
2934	Test Dummies and Requirements for Testing Child Restraint Systems .....	2127-AF02
2935	Conversion of Measurements From English Units to Metric Units .....	2127-AF03
2936	Replaceable Light Source Information .....	2127-AF07
2937	Heavy Vehicle Burnish Procedures .....	2127-AF13
2938	Maximum Inflation Pressure for Tires .....	2127-AF19
2939	Pneumatic Timing and Balance for Trailer Brake Systems .....	2127-AF23
2940	School Bus Driving Mirrors .....	2127-AF31
2941	Strobe Lights on School Bus Stop Arms .....	2127-AF32
2942	Seat Belt Anchorage in Small Buses .....	2127-AF33
2943	Air Bag Warning Label Requirements .....	2127-AF39

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## National Highway Traffic Safety Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
2944	Requirements for Use of Compressed Natural Gas	2127-AF42

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.  
 \* DOT-designated significant regulation

## National Highway Traffic Safety Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
2945	*Compressed Natural Gas (CNG)	2127-AD48
2946	*Certification of Speed Limit Enforcement	2127-AE52
2947	*American Automobile Labeling Act Requirements	2127-AE63
2948	*Light Truck Average Fuel Economy Standards for Model Years (MY) 1996 and 1997	2127-AE91
2949	Emergency Locking Retractors	2127-AC57
2950	Seating Systems Test Procedure	2127-AD09
2951	Tire Labeling, FMVSS 109, 110, 117, 119, 120; Parts 569, 574, 575	2127-AD28
2952	Controls and Displays and Windshield Defrosting and Defogging Systems for Electric Vehicles	2127-AE29
2953	Head Injury Criterion and Use of Neck Injury Criterion	2127-AE34
2954	Child Booster Seats	2127-AE39
2955	Safety Belt Design	2127-AE48
2956	Petitions and Plans for Relief Under the Automobile Fuel Efficiency Act of 1980	2127-AE65
2957	Procedures for Selecting Lines To Be Covered by the Theft Prevention Standard	2127-AE67
2958	Maximum Inflation Pressure	2127-AE70
2959	Del. Code Requirements	2127-AE74
2960	Automatic Brake Adjustment Limits	2127-AE76
2961	Applicability of Warning Devices	2127-AE78
2962	Belt Labeling Requirements	2127-AE79
2963	Center High Mounted Stop Lamps for Light Trucks	2127-AE96
2964	Dynamic Testing for Built-In Child Restraint Systems	2127-AF04
2965	Exemption of Vehicles Used by the Handicapped	2127-AF09
2966	Replacement Seat Belt Assemblies Installation Instructions	2127-AF10
2967	Specifications for Light Emitting Diode	2127-AF20
2968	Trailer conspicuity	2127-AF21
2969	Advanced Brake Light Warning System	2127-AF26
2970	Anthropomorphic Test Dummy	2127-AF26
2971	Final Listing of High-Theft Lines for Model Year (MY) 1995	2127-AF34

\* DOT-designated significant regulation.

## Federal Railroad Administration—Preamble Stage

Sequence Number	Title	Regulation Identifier Number
2972	*Whistle Bans at Highway-Rail Grade Crossings	2130-AA71
2973	*Generic Standards for Corridors up to 160 MPH (Reg Plan Seq. No. 129)	2130-AA86
2974	*Locomotive Crashworthiness and Working Conditions	2130-AA86

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.  
 \* DOT-designated significant regulation.

## Federal Railroad Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
2975	*Power Brake Regulations; Miscellaneous Revisions	2130-AA73
2976	*Track Safety Standards	2130-AA75
2977	*Rules on Protection of Maintenance-of-Way Employees	2130-AA86

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## Federal Railroad Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
2978	+Environmental Impact and Related Procedures (FRA, FTA, FHWA) .....	2130-AA93
2979	Railroad Accident Reporting .....	2130-AA58
2980	Alcohol/Drug Regulations; Miscellaneous Technical Amendments and Corrections .....	2130-AA83
2981	Qualification and Certification of Locomotive Engineers .....	2130-AA74
2982	Locomotive Conspicuity; Minimum Standards for Auxiliary External Lights .....	2130-AA80
2983	AMTRAK Waste Disposal .....	2130-AA84
2984	Event Recorders .....	2130-AA87
2985	Protection of Utility Employees .....	2130-AA90
2986	Selection and Installation of Grade Crossing Warning Systems .....	2130-AA82

+ DOT-designated significant regulation.

## Federal Railroad Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
2987	+Freight Car Safety Standards: Maintenance-of-Way Equipment .....	2130-AA68
2988	Centralization of Formal Hearing Dockets (FRA) .....	2130-AA59
2989	Local Rail Freight Assistance to States .....	2130-AA60

+ DOT-designated significant regulation.

## Federal Railroad Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
2990	+Timely Response to Grade Crossing Signal System Malfunctions and Maintenance, Inspection, and Testing of Grade Crossing Signal Systems .....	2130-AA70
2991	Railroad Operating Rules and Radio Standards and Procedures .....	2130-AA76
2992	Remedial Actions Reporting .....	2130-AA85
2993	Bridge Worker Safety Standards .....	2130-AA91

+ DOT-designated significant regulation.

## Federal Transit Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
2994	+Department of Transportation (FTA, FRA, FHWA) Environmental Impact and Related Procedures .....	2132-AA43
2995	Transportation for the Elderly and Persons With Disabilities .....	2132-AA46

+ DOT-designated significant regulation.

## Federal Transit Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
2996	+Bus Testing .....	2132-AA30
2997	+State Responsibility for Fixed-Guideway System Safety (Reg Plan Seq. No. 130) .....	2132-AA39
2998	+Management and Monitoring Systems .....	2132-AA47
2999	+Temporary Local Match Waiver for Sections 9 and 18 .....	2132-AA49
3000	+New Starts Criteria .....	2132-AA50
3001	Buy America .....	2132-AA42

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.

+ DOT-designated significant regulation.

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## Federal Transit Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
3002	*Notice of Final Action on Proposed Revision of Private Enterprise Participation Guidance	2137-AA-97

\* DOT-designated significant regulation

## Research and Special Programs Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
3003	Consolidation of Specifications for High Pressure Seamless Cylinders and Rewrite of 49 CFR 173.34	2137-AA92
3004	Modernizing the Passenger Origin-Destination Survey	2137-AB92
3005	Approval of Multi-Unit Tank Car Tanks	2137-AC41

## Research and Special Programs Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
3006	*Gas Gathering Line Definition	2137-AB15
3007	*Qualification of Pipeline Personnel	2137-AB38
3008	*Maps and Records of Pipeline Location and Characteristics; Notification of State Agencies; Pipe Inventory	2137-AB48
3009	*Improvements to Hazardous Materials Identification Systems (Reg Plan Seq. No. 131)	2137-AB75
3010	*Infectious Substances	2137-AC36
3011	*Increased Inspection Requirements (Reg Plan Seq. No. 132)	2137-AC38
3012	*Emergency Flow-Restricting Devices (Reg Plan Seq. No. 133)	2137-AC39
3013	DOT 3AL Aluminum Cylinders; Safety Problems	2137-AB51
3014	Passage of Internal Inspection Devices	2137-AB71
3015	Design and Construction of Welded Breakout Tanks	2137-AC11
3016	Underwater Abandoned Pipeline Facilities	2137-AC33
3017	Environmentally Sensitive Areas and High-Density Population Areas	2137-AC34
3018	Transportation of Hazardous Materials; Miscellaneous Amendments	2137-AC41
3019	Incorporation of Latest United Nations Recommendations on the Transport of Dangerous Goods	2137-AC42
3020	Safety Permits—Shipper's Responsibility	2137-AC45
3021	Labeling Requirements for Poisonous Materials	2137-AC47
3022	Review of Confidentiality Requirements for Schedule T-100 Domestic Market Data	2137-AC49
3023	Hazardous Liquid Gathering Line Definition	2137-AC52
3024	Regulated Gas and Hazardous Liquid Gathering Lines	2137-AC53
3025	Permanent Underwater Inspections	2137-AC54
3026	Excess Flow Valve Customer Notification	2137-AC55
3027	Mandatory One-Call Participation	2137-AC57

References in boldface appear in the Regulatory Plan in Part II of this issue of the Federal Register.

\* DOT-designated significant regulation

## Research and Special Programs Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
3028	*Hazardous Materials in Intrastate Commerce	2137-AB37
3029	*Excavation Damage Prevention Programs for Gas and Hazardous Liquid Pipelines	2137-AB47
3030	*Crashworthiness Protection Requirements for Tank Cars	2137-AB89
3031	*Excess Flow Valves in Service Lines	2137-AB97
3032	*Safeguarding Food From Contamination During Transportation	2137-AC06
3033	*Regulatory Review: Gas Pipeline Safety Standards	2137-AC25
3034	*Response Plans for Onshore Oil Pipelines	2137-AC30
3035	*Oil Spill Prevention and Response Plans	2137-AC31
3036	Quantity Limitations Aboard Aircraft	2137-AA85
3037	Enforcement of Motor Carrier Financial Responsibility Requirement	2137-AB35

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## Research and Special Programs Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
3038	Detection and Repair of Cracks, Pits, Corrosion, Lining Flaws, Thermal Detection Flaws, and Other Defects of Tank Car Tanks .....	2137-AB40
3039	Determining the Extent of Corrosion on Exposed Gas Pipelines .....	2137-AB50
3040	Transportation Regulations; Compatibility with the International Atomic Energy Agency .....	2137-AB60
3041	Transportation of Hydrogen Sulfide by Pipeline .....	2137-AB63
3042	Tank Cars and Cargo Tank Motor Vehicles: Attendance Requirements .....	2137-AC24
3043	Hazardous Materials in COFC/TOFC Service .....	2137-AC26
3044	Regulatory Review: Administrative Practices, Reporting Pipeline Incidents, Gas Pipeline Standards, and Liquefied Natural Gas Facility Standards .....	2137-AC28
3045	Customer-Owned Service Lines .....	2137-AC32
3046	Cargo Tanks; Miscellaneous Requirements .....	2137-AC37

+ DOT-designated significant regulation.

## Research and Special Programs Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
3047	+Pressure Testing of Certain Hazardous Liquid and Carbon Dioxide Pipelines .....	2137-AB46
3048	+Transportation of Hazardous Liquids at 20 Percent or Less of Specified Minimum Yield Strength .....	2137-AB86
3049	+Amendments to the DOT Airline On-Time Disclosure Rule .....	2137-AC94
3050	Review of Commercial Air Traffic and Market Data Reporting .....	2137-AB18
3051	Intermediate Bulk Containers for Hazardous Materials .....	2137-AC23
3052	Regulatory Review: Hazardous Liquid and Carbon Dioxide Pipeline Safety Standards .....	2137-AC27
3053	Transportation of Hazardous Materials; Miscellaneous Editorial Corrections .....	2137-AC44
3054	Hazardous Materials; Miscellaneous Revisions .....	2137-AC46
3055	Exemption From Property Tariff Filing Requirements .....	2137-AC48
3056	Hazardous Materials Registration and Fee Assessment Program .....	2137-AC50
3057	Hazardous Substances .....	2137-AC56

+ DOT-designated significant regulation.

## Maritime Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
3058	+Cargo Preference—U.S.-Flag Vessels; Uniform Contracting Requirements for Federal Program Participants (Reg Plan Seq. No. 134) .....	2133-AA95
3059	+Obligation Guarantees; Program Administration .....	2133-AB14
3060	Foreign Transfer of Documented Vessels .....	2133-AB11
3061	Cargo Preference—U.S.-Flag Vessels; Monitoring Shipments of Military Household Goods and Personal Effects .....	2133-AB12
3062	Federal Port Controllers .....	2133-AB15

References in boldface appear in the Regulatory Plan in Part II of this issue of the **Federal Register**.

+ DOT-designated significant regulation.

## Maritime Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
3063	Centralization of Formal Hearing Dockets (MARAD) .....	2133-AA84
3064	Values for War Risk Insurance; Review of War Risk Insurance Valuation Methodology .....	2133-AA89

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## Maritime Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
3065	*Obligation Guarantees	2133-AB09
3066	*Cargo Preference—U.S.-Flag Vessels, Available U.S.-Flag Commercial Vessels	2133-AB13
3067	Merchant Marine Training	2133-AA94
3068	Seamen's Service Awards	2133-AB02

+ DOT-designated significant regulation.

## DEPARTMENT OF TRANSPORTATION (DOT)

Prerule Stage

## Office of the Secretary (OST)

## 2519. DIRECT FLIGHTS

**Legal Authority:** 49 USC 1381**CFR Citation:** 14 CFR 399**Legal Deadline:** None

**Abstract:** Donald L. Pevsner petitioned the CAB to institute a rulemaking proceeding to ban use of the term "direct flight" because it is deceptive, and to declare use of the term to be a prima facie violation of section 411 of the Federal Aviation Act of 1958. The Department is now considering what action to take in response to the petition.

**Timetable:** Next Action Undetermined**Small Entities Affected:** None**Government Levels Affected:** None**Additional Information:** The petition is filed in Docket #1217.

**Agency Contact:** Joanne Petrie, Attorney, Department of Transportation, Office of the Secretary, 400 Seventh Street SW., Washington, DC 20590, 202 366-9306

**RIN:** 2105-AA73

## 2520. PRICE ADVERTISING

**Legal Authority:** 49 USC 1371; 49 USC 1381**CFR Citation:** 14 CFR 380.30(e); 14 CFR 399.84**Legal Deadline:** None

**Abstract:** The DOT rules cited above state that any price stated for air transportation, a tour or a tour component must be the entire price for that transportation, tour or component.

In this petition, Mr. Donald Pevsner complains that some tour operators advertise prices which do not include additional features which must be purchased and which cost extra. He asks that the rules be amended to state that such additional features may only be priced separately if they may be purchased separately, i.e., if they are optional rather than mandatory. The petition is under consideration.

**Timetable:**

Action	Date	FR Cite
Petition for Rulemaking (Dkt 43147)	05/22/85	

Next Action Undetermined

**Small Entities Affected:** Businesses**Government Levels Affected:** None

**Agency Contact:** Joanne Petrie, Attorney, Department of Transportation, Office of the Secretary, 400 Seventh Street SW., Washington, DC 20590, 202 366-9306

**RIN:** 2105-AB25

## 2521. IMPLEMENTATION OF AMENDMENTS TO THE EQUAL ACCESS TO JUSTICE ACT

**Legal Authority:** 5 USC 504**CFR Citation:** 49 CFR 6; 48 CFR 6301; 14 CFR 14**Legal Deadline:** None

**Abstract:** This action would incorporate the latest amendments to the Equal Access to Justice Act (EAJA or "Act"), 5 USC 504, into OST's EAJA regulations, 49 CFR 6. The EAJA provides for the award of attorneys' fees and other expenses to eligible individuals and entities who prevail over the Government in administrative proceedings, unless the position of the Government was substantially justified. The latest amendment made certain technical and substantive amendments to the EAJA, as well as made the Act, as so amended, permanent. This rulemaking is undertaken at the Department's initiative in response to the statutory changes in the EAJA.

**Timetable:** Next Action Undetermined**Small Entities Affected:** None**Government Levels Affected:** None**Analysis:** Regulatory Evaluation

**Agency Contact:** Joanne Petrie, Attorney, Department of Transportation, Office of the Secretary, 400 Seventh Street SW., Washington, DC 20590, 202 366-9306

**RIN:** 2105-AB73

**Department of Transportation**  
**Office of the Secretary**  
**Washington, D.C.**

**ORDER**

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**SUBJECT: POLICIES AND PROCEDURES FOR SIMPLIFICATION, ANALYSIS, AND REVIEW OF REGULATIONS**

1. PURPOSE. This Order establishes objectives to be pursued in reviewing existing regulations and in issuing new regulations; prescribes procedures and assigns responsibilities to meet those objectives; and establishes a Department Regulations Council to assist and advise the Secretary in achieving those objectives and improving the quality of regulations and the policies and practices which affect the formulation of regulations.
2. CANCELLATION. DOT 2050.4, Procedures for Considering Inflationary Impact, of 2/2/76. Policies to Improve Analysis and Review of Regulations, of 4/13/76. DOT 1100.60, Figure I-C, controls requiring the head of an operating administration to coordinate notices of proposed rulemaking and regulations with the Office of the Secretary and which are listed in the table of Control of Certain Powers and Duties, of 3/7/79 (originally published as DOT 1100.23A, 12/17/74).

3. SCOPE.

This Order applies to the Office of the Secretary (OST), the United States Coast Guard (USCG), the Federal Aviation Administration (FAA), the Federal Highway Administration (FHWA), the Federal Railroad Administration (FRA), the National Highway Traffic Safety Administration (NHTSA), the Urban Mass Transportation Administration (UMTA), the St. Lawrence Seaway Development Corporation (SLSDC), and the Research and Special Programs Administration (RSPA).

4. EFFECTIVE DATE. 3/1/79.

5. REFERENCES.

- a. Title 5, United States Code, section 552(a)(1) and 553 which prescribe general procedural requirements of law applicable to all Federal agencies regarding the formulation and issuance of regulations.
- b. Executive Order 12044 of 3/23/78, "Improving Government Regulations", which prescribes general policy and procedural requirements applicable to all Federal executive agencies regarding the improvement of existing and future regulations.

**DISTRIBUTION: All Secretarial Offices**  
**All Operating Administrations**

**OPI: Assistant General**  
**Counsel for Regulation**  
**and Enforcement**

- c. Presidential memoranda of 3/23/78, and 2/25/77, which prescribe general policy and procedural requirements applicable to all Federal executive agencies regarding State and local government participation in the development and promulgation of significant Federal regulations having a major intergovernmental impact.
- d. "Improving Government Regulations; Regulatory Policies and Procedures," 44 FR 11034 of 3/1/79.
- e. Amendment to "Improving Government Regulations; Regulatory Policy and Procedures," 44 FR 28126 of 5/14/79.

6. COVERAGE.

a. Definitions.

- (1) Initiating office means an operating administration or other organizational element within the Department, the head of which is authorized by law or delegation to issue regulations or to formulate regulations for issuance by the Secretary.
- (2) Significant regulation means a regulation that is not an emergency regulation and that in the judgment of the head of the initiating office, or the Secretary, or the Deputy Secretary:
  - (a) Requires a Regulatory Analysis under paragraph 10a of this Order or is otherwise costly;
  - (b) Concerns a matter on which there is substantial public interest or controversy;
  - (c) Has a major impact on another operating administration or other parts of the Department or another Federal agency;
  - (d) Has a substantial effect on state and local governments;
  - (e) Has a substantial impact on a major transportation safety problem;
  - (f) Initiates a substantial regulatory program or change in policy;

(g) Is substantially different from international requirements or standards; or

(h) Otherwise involves important Department policy.

(See paragraph 10a of this Order for factors to consider in applying this definition.)

(3) Emergency regulation means a regulation that:

(a) In the judgment of the head of the initiating office, circumstances require to be issued without notice and opportunity for public comment or made effective in less than 30 days after publication in the Federal Register; or

(b) Is governed by short-term statutory or judicial deadlines.

(4) Nonsignificant regulation means a regulation that in the judgement of the head of the initiating office is neither a significant nor an emergency regulation.

b. Applicability.

(1) This Order applies to all rules and regulations of the Department, including those which establish conditions for financial assistance.

(2) This Order does not apply to:

(a) Any rulemaking in which a notice of proposed rule-making was issued before the effective date of this Order and which was still in progress on that date;

(b) Regulations issued in accordance with the formal rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 556, 557):

(c) Regulations issued with respect to a military or foreign affairs function of the United States;

(d) Matters related to agency management or personnel; or

(e) Regulations related to Federal Government procurement.

7. OBJECTIVES.

To simplify and improve the quality of regulations, it is the policy of the Department that the following objectives be pursued in issuing new regulations and continuing existing regulations:

- a. Necessity. A regulation should not be issued or continue in effect unless it is based on a well-defined need to address a specific problem.
- b. Clarity. A regulation and any supplemental material explaining it should be clear, precise, and understandable to all who may be affected by it.
- c. Simplicity. A regulation should be as short and uncomplicated as possible; before issuance, it should be coordinated as required within the Department and between the Department and other Federal agencies to eliminate or minimize unnecessary duplication, inconsistency, and complexity; it should be issued only after compliance costs, paperwork and other burdens on the public are minimized.
- d. Timeliness. A regulation should be issued in time to respond to the circumstances that require it and should be modified or cancelled as those circumstances change.
- e. Reasonableness. A regulation should provide a feasible and effective means for producing the desired results; it should be developed giving adequate consideration to the alternatives, to anticipated safety, environmental, social, energy, economic, and legal consequences, and to anticipated indirect effects; it should not impose an unnecessary burden on the economy, on individuals, on public or private organizations, or on State and local governments.
- f. Fairness. Generally, a regulation should be issued only after a reasonable and timely opportunity has been provided for all interested persons to comment on it.

8. DEPARTMENT REGULATIONS COUNCIL.

- a. Membership; Chair and Vice-Chair. A Department Regulations Council is hereby established comprised as follows:

Regular Members:

- (1) The Deputy Secretary -- Chair
- (2) General Counsel -- Vice-Chair
- (3) Assistant Secretary for Policy and International Affairs
- (4) Assistant Secretary for Budget and Programs
- (5) Assistant Secretary for Administration
- (6) Assistant Secretary for Governmental Affairs
- (7) Director, Office of Public Affairs
- (8) Director, Departmental Office of Civil Rights

Ex Officio Members:

- (1) Commandant of the Coast Guard
- (2) Federal Aviation Administrator
- (3) Federal Highway Administrator
- (4) Federal Railroad Administrator
- (5) National Highway Traffic Safety Administrator
- (6) Urban Mass Transportation Administrator
- (7) Saint Lawrence Seaway Development Corporation Administrator
- (8) Research and Special Programs Administrator

b. Functions and responsibilities. The Council:

- (1) Monitors initiating offices' programs for reviewing and revising their existing regulations and makes recommendations to the heads of initiating offices and the Secretary when appropriate with regard to the conduct and effectiveness of those programs;

- (2) Considers each significant regulation referred to it and makes such recommendations as the members consider appropriate regarding the advisability of the Secretary's concurring in its issuance;
  - (3) On its own initiative or upon request, reviews, discusses, and makes such recommendations to the Secretary as the members consider appropriate regarding Department regulatory policies and procedures; and
  - (4) In coordination with the initiating office(s) concerned, designates such task forces or requires the preparation of such reports, analyses, or options papers as it considers necessary for proper Council consideration of any regulatory matter or inquiry referred to or initiated by the Council.
- c. Staff support. The General Counsel provides regular staff support to the Council and designates an Assistant General Counsel to be responsible for performing the functions assigned to the General Counsel's office. These include the coordination of the staffing, analysis, and review of items coming before the Council or on which the Council requires additional information; the convening and management of task forces designed to review and improve major categories of existing regulations; and such additional duties as the Council may specify.
- d. Meetings; attendance of members. The Council meets on a regular bi-monthly basis. It also meets on special occasions, at the call of the Chair, either on his or her own initiative or at the request of the head of an initiating office. Attendance by ex officio members is optional. Any member who is unable to attend a meeting may be represented at the meeting only by the member's principal deputy or Chief Counsel. A member may be accompanied by supporting staff for purposes of briefing the Council or assisting the member with respect to an agenda item or a significant regulation scheduled for discussion.
- e. Agenda. The General Counsel's office prepares an agenda for each meeting and distributes it to the members in advance of the meeting, together with any documents to be discussed at the meeting. When the agenda includes consideration of a significant regulation, the General Counsel's office makes

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such arrangements with the initiating office as may be appropriate for briefing the Council and responding to questions concerning the regulation.

- f. Minutes. The General Counsel's office prepares summary minutes following each meeting and distributes them to the members.

9. RESPONSIBILITIES OF INITIATING OFFICES.

- a. The head of each initiating office is primarily responsible for:
- (1) Reviewing proposed regulations to ensure that they meet the objectives set forth in paragraph 7 of this Order;
  - (2) Issuing regulations within the scope of his or her statutory or delegated authority;
  - (3) Coordinating proposed regulations with other Federal agencies and other operating administrations and organizational elements within the Department; and
  - (4) In conjunction with the Assistant Secretary for Governmental and Public Affairs, consulting with State and local governments as required under the memoranda referenced in paragraph 5c of this Order in the development of regulations to be issued by that office.
- b. To improve the quality of existing and future regulations in accordance with the purposes and policies set forth in this Order, the head of each initiating office:
- (1) Establishes and carries out a program for reviewing and revoking or revising existing regulations in accordance with paragraph 12 of this Order;
  - (2) Includes in the public docket for each proposed regulation a draft Regulatory Analysis or Evaluation as required under paragraph 11 of this Order;
  - (3) Includes in the public docket for each final regulation a final Regulatory Analysis or Evaluation as required under paragraph 11 of this Order;
  - (4) Submits Regulations Reports to the Department Regulations Council in accordance with paragraph 14a of this Order;

- (5) Submits for the Secretary's concurrence, before issuance, regulatory documents pertaining to significant regulations, together with such supporting documentation as may be required by paragraph 10 of this Order;
- (6) Advises the Secretary by memorandum, before issuance if possible, of the circumstances requiring emergency issuance of an otherwise significant regulation;
- (7) Names a Regulations Officer to coordinate the review of regulations and act as principal staff liaison with the Council; and
- (8) Informs the Deputy Secretary or the General Counsel of any regulatory matter that should be reviewed by or coordinated with the Council.

10. REVIEW OF SIGNIFICANT REGULATIONS.

- a. In determining whether a regulation is significant, the following things, among others, are considered:
  - (1) The type and number of individuals, businesses, organizations, and State and local governments affected;
  - (2) The compliance and reporting requirements likely to be involved;
  - (3) Direct and indirect effects of the regulation including the effect on competition; and
  - (4) The relationship of the regulations to those of other programs and agencies.

Proposed and final regulations that are not considered significant under this Order are accompanied by a statement in the Federal Register to that effect.

- b. Before an initiating office proceeds to develop a significant regulation, the head of the initiating office considers the need for the regulation, the major issues involved and the alternative approaches to be explored. If he or she determines that further action is warranted, the initiating office then prepares a Work Plan. The Work Plan states or describes:

- (1) The need for the regulation;
- (2) The objective(s) of the regulation;
- (3) The legal authority for the regulation;
- (4) The names of the individual or organizational unit primarily responsible for developing the regulation and of the accountable official;
- (5) Whether a Regulatory Analysis is likely to be required and how and where it will be produced;
- (6) The probable reporting requirements (direct or indirect) that may be involved;
- (7) A tentative plan for how and when the Congress, interest groups, other agencies, and the general public will have opportunities to participate in the regulatory process; and
- (8) The tentative target dates for completing each step in the development of the regulation.

If the Work Plan is approved by the head of the initiating office, the development of the significant regulation may proceed.

- c. As soon as it is approved, the Work Plan is submitted to the General Counsel for his or her information.
- d. Before issuing for publication in the Federal Register any regulatory document of substantive significance (e.g., advance notice of proposed rulemaking, notice of withdrawal, supplemental notice or final rule) or a notice of an exclusively procedural nature (e.g., extending time for comments or scheduling a public hearing) pertaining to a significant regulation, the initiating office submits it to the Secretary for concurrence.
- e. To receive Secretarial concurrence for the issuance of any regulatory document of substantive significance pertaining to a significant regulation, the initiating office submits it to the General Counsel's office at least 30 days before the proposed date of issuance; included with this submission

is (1) an approved Work Plan, (2) a draft or final Regulatory Analysis or Evaluation, and (3) a summary of the results of any coordination outside the initiating office. Once a Work Plan and Regulatory Analysis or Evaluation is developed for a particular significant regulation, they are only updated and supplemented for successive regulatory documents pertaining to that significant regulation. In the case of a final rule submitted for Secretarial concurrence, there is an accompanying summary of meaningful public comments received.

- f. Before submitting a final rule for Secretarial concurrence, the head of the initiating office reviews all the documents required to be submitted and determines that, at a minimum:
  - (1) The regulation is needed;
  - (2) The direct and indirect effects of the regulation have been adequately considered;
  - (3) Alternative approaches have been considered and the least burdensome of the acceptable alternatives has been chosen;
  - (4) Public comments have been considered and an adequate response has been prepared;
  - (5) The regulation is written in plain English and is understandable to those who must comply with it;
  - (6) An estimate has been made of the new reporting burdens or recordkeeping requirements necessary for compliance with the regulation;
  - (7) The name, address and telephone number of a knowledgeable agency official is included in the publication; and
  - (8) A plan for evaluating the regulation after its issuance has been developed.
- g. The General Counsel's office distributes each regulatory document and accompanying supporting documents received from an initiating office under paragraph 10d of this Order to all appropriate Secretarial Officers for review and coordinates their comments and recommendations for transmittal, together with a staff analysis, to the Secretary through the Deputy Secretary.

- h. The Deputy Secretary or the General Counsel may refer a significant regulation to the Department Regulations Council for its consideration at its next regular or special meeting. This is done if, in the judgment of the Deputy Secretary or the General Counsel, the views of the Council on that regulation are desirable or likely to assist the Secretary in determining whether to concur in its issuance. Council consideration of a significant regulation is in addition to and not in lieu of Secretarial staff review; both are scheduled and coordinated so as to minimize delay in transmitting the resulting recommendations to the Secretary.
- i. To receive Secretarial concurrence for the issuance of any notice of an exclusively procedural nature pertaining to a significant regulation, the initiating office submits a copy of the notice to the General Counsel's office at least 3 days before the intended date of issuance; included with this submission is a memorandum which specifies the intended date of issuance, states why the notice is required and describes any changes that it will cause in the previously anticipated schedule of action dates on the significant regulation concerned.
- j. The General Counsel may concur for the Secretary in the issuance of a procedural regulatory document received from an initiating office under paragraph 10i of this Order, when warranted. The General Counsel advises the Secretary through the Deputy Secretary of such actions as soon as possible. For all other such documents, the General Counsel's office advises the Secretary through the Deputy Secretary of each document received. Unless otherwise notified before the intended date of issuance, Secretarial concurrence may be presumed.
- k. For an emergency regulation that otherwise would be significant, the initiating office includes with the regulation when published in the Federal Register, a statement of the reasons why it is impracticable or contrary to the public interest for the initiating office to follow the procedures of this Order and Executive Order 12044. Such a statement includes the name of the policy official responsible for this determination.
- l. If, at any time during its development, the head of the initiating office determines that a regulation classified as significant should be reclassified as nonsignificant, he or

she submits a memorandum providing the basis for the recommended change to nonsignificant to the Secretary for concurrence. The regulation continues to be handled as significant unless the Secretary concurs in the change.

11. REGULATORY ANALYSES AND EVALUATIONS.

- a. Except as indicated in paragraph 11g of this Order, an initiating office prepares and places in the public docket a draft Regulatory Analysis for each of its proposed regulations that:
  - (1) Will result in an annual effect on the economy of \$100 million or more;
  - (2) Will result in a major effect on the general economy in terms of costs, consumer prices, or production;
  - (3) Will result in a major increase in costs or prices for individual industries, levels of government, or geographic regions;
  - (4) Will have a substantial impact on the United States balance of trade; or
  - (5) The Secretary or head of the initiating office determines deserves such analysis.
- b. Each draft Regulatory Analysis contains:
  - (1) A succinct statement of the problem and the issues that make the regulation significant;
  - (2) A description of the major alternative ways of dealing with the problem that were considered by the initiating office;
  - (3) An analysis of the economic and any other relevant consequences of each of these alternatives; and
  - (4) A detailed explanation of the reasons for choosing one alternative over the others.
- c. A draft Regulatory Analysis addresses all salient points to the maximum extent possible. If data are lacking or there are questions about how to determine or analyze points of interest,

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the problem is noted in the draft Regulatory Analysis; to help elicit the necessary information during the public comment period on the advance notice or notice of proposed rulemaking, the appropriate questions are included in the advance notice or notice of proposed rulemaking.

- d. The initiating office includes in each advance notice or notice of proposed rulemaking on a proposal requiring a Regulatory Analysis, an explanation of the regulatory approach being considered or proposed, a short description of the alternative approaches, and a statement of how the public may obtain a copy of the draft Regulatory Analysis for review and comment.
- e. An initiating office prepares and places in the public docket for each of its proposed regulations not requiring a draft Regulatory Analysis, a draft Evaluation. This Evaluation includes an analysis of the economic consequences of the proposed regulation, quantifying, to the extent practicable, its estimated cost to the private sector, consumers, Federal, State and local governments, as well as its anticipated benefits and impacts. Judgment is exercised by the head of the initiating office so that resources and time devoted to the Evaluation reflect the importance of the proposal. The initiating office includes in each advance notice or notice of proposed rulemaking requiring an Evaluation a statement of how the public may obtain a copy of the draft Evaluation for review and comment. If the head of the initiating office determines that the expected impact is so minimal that the proposal does not warrant a full Evaluation, a statement to that effect and the basis for it is included in the proposed regulation; a separate statement is not placed in the public docket. For a significant regulation, the Evaluation also includes a succinct statement of the issues which make the regulation significant and an analysis of any other relevant consequences.
- f. The initiating office prepares a final Regulatory Analysis for each final regulation that meets the criteria of paragraph 11a of this Order; otherwise, a final Evaluation, in accordance with the requirements of paragraph 11e of this Order, is prepared. The Regulatory Analysis or the Evaluation is placed in the public docket at the time of or before issuing the final regulation and the regulation is accompanied by a statement of how the public may obtain a copy of the Regulatory Analysis or the Evaluation for review.

- g. An emergency regulation that otherwise would be nonsignificant is excepted from the requirements for any Evaluation. For an emergency regulation that otherwise would be significant, the initiating office prepares and places in the public docket as soon as possible after issuance of the notice or final regulation a Regulatory Analysis or Evaluation, whichever is appropriate, unless an exception is granted by the Secretary.

12. REVIEW AND REVISION OF EXISTING REGULATIONS.

- a. Each initiating office establishes a program for reviewing its existing regulations and revoking or revising those regulations that it determines are not achieving their intended purposes. This review follows the same procedural steps for the development of new regulations.
- b. In identifying existing regulations for review and possible revocation or revision and in determining the order in which they are to be reviewed, an initiating office considers:
  - (1) The nature and extent of complaints or suggestions (including petitions for rulemaking) received, especially ones received from those directly or indirectly affected by the regulations;
  - (2) The need to simplify or clarify language; consideration should especially be given to the number of requests received for interpretations or the problems evidenced in the enforcement of the regulation;
  - (3) The need to eliminate overlapping and duplicative regulations;
  - (4) The need to eliminate conflicts and inconsistencies in its own regulations or those of other initiating offices or other agencies;
  - (5) The length of time since the regulations were last reviewed or evaluated;
  - (6) The importance and continued relevance of the problem the regulations were originally intended to solve;
  - (7) The burdens imposed on those directly or indirectly affected by the regulations;

- (8) The degree to which technology, economic conditions or other factors have changed in the area affected by the regulation; and
- (9) The number of requests received for exemption from a regulation and the number granted.
- c. Each initiating office prepares a list of the existing regulations it has selected for review and possible revocation or revision. It includes (1) a brief description of the reasons for each selection, (2) a target date for completing the review and determining the course of corrective action to be taken, and (3) the name and telephone number of a knowledgeable initiating office official who can provide additional information. The list of existing regulations selected is submitted to the Department Regulations Council through the General Counsel. It is updated as part of the initiating office's semi-annual Regulations Report and the supplements required under paragraph 14 of this Order. The semi-annual report includes any final action taken or determination made since the last list.
- d. The General Counsel's office consolidates the initiating offices' lists of existing regulations selected for review for the Council and from that consolidation prepares a semi-annual list for publication in the Federal Register as part of the Department Regulations Agenda. Federal Register publication is for the stated purpose of sharing information with interested members of the public. Choosing to review a regulation does not indicate that it will be discarded or that it will not be enforced while under review.

### 13. OPPORTUNITY FOR PUBLIC PARTICIPATION.

- a. Initiating offices should take appropriate steps, including the following, to increase the opportunity for public participation:
  - (1) In addition to publishing proposals and notices of regulatory actions in the Federal Register, an initiating office should, in appropriate circumstances, provide a clear, concise notice to publications likely to be read by those affected, and, to the extent practical, notify interested parties directly.

- (2) If the subject is unusually complex, or if there is a considerable potential for adverse effects from a failure to provide an opportunity for early public participation, the initiating office should consider supplementing the minimum rulemaking steps required by section 553 of Title 5, United States Code. For example, an advance notice of proposed rulemaking may be employed to solicit comments and suggestions on an upcoming notice of proposed rulemaking or an open conference may be held at which a discussion between all interested parties would help narrow or clarify issues. However, such supplementary procedures should be used only when they will serve to clarify the issues and enhance effective public participation. They should not be used if they would delay the process of developing the regulations unless significant additional information is to be gained by the initiating office or the public.
- (3) When appropriate, an initiating office may solicit views through surveys or panels.
- (4) When the issues involved warrant it and time permits, an initiating office should allow time for the public to submit rebuttal to comments submitted in response to proposals.
- (5) To the extent permissible, an initiating office may consider providing financial assistance to persons who lack the resources to participate meaningfully in its regulatory proceedings.
- (6) An initiating office should identify, in a statement accompanying a proposed or final regulation, the nature of the research relied on to support a particular regulatory approach; the statement should clearly indicate the importance of the research in the development of the regulation; and the source material should be made available for public review by placing a copy in the public docket.
- (7) As necessary, the Department, and its initiating offices, provides information and instruction through public meetings and publications, in the use of its regulatory policies and procedures, especially with respect to public participation.

- b. The public is provided at least 60 days to comment on proposed significant regulations. In the few instances where the initiating office determines this is not possible, the proposal is accompanied by a brief statement of the reasons for a shorter time period.
- c. The public is generally provided at least 45 days to comment on proposed nonsignificant regulations. When at least 45 days are not provided, the proposal or the regulation is accompanied by a brief statement of the reasons.
- d. To the maximum extent possible, notice and an opportunity to comment on regulations should be provided to the public, even when not required by statute, if such action could reasonably be anticipated to result in the receipt of useful information. When an initiating office does not provide notice and an opportunity for the public to comment, (1) a statement of the reasons is included with the final regulation when it is published in the Federal Register and (2) when reasonable, the initiating office should provide notice and opportunity to comment subsequent to the final regulation. This action can be taken in conjunction with a plan for evaluating the regulation after its issuance.
- e. If any of the national organizations representing general purpose State and local governments (including the National Governor's Association, the National Conference of State Legislatures, the Council of State Governments, the National League of Cities, the United States Conference of Mayors, the National Association of Counties, and the International City Management Association) notifies the department, including any of its initiating offices, that it believes a regulation included on the Department's Regulations Agenda would have major intergovernmental impact, the initiating office develops a specific plan, in conjunction with the Assistant Secretary for Governmental and Public Affairs, for consultation with the State and local governments in the development of that regulation. Such consultation includes the solicitation of comments from the above named groups, from other representative organizations and from individual State and local governments as appropriate. In determining appropriate action, to help ensure the practicability and effectiveness of the programs, the initiating office considers the following:

- (1) State and local sectors constitute the delivery mechanisms for most of the actual services the Federal Government provides;
- (2) State and local sectors have concerns and expertise;
- (3) Early participation by State and local officials in the planning process helps ensure broad-based support for the proposals that are eventually developed; and
- (4) Early participation also ensures that priorities developed at the Federal level will work in conjunction with and not at cross-purposes to priorities at the State and local level.

Whenever a significant proposed regulation identified as having a major intergovernmental impact, is submitted to the Office of Management and Budget for review or is published in the Federal Register, it is accompanied by a brief description of (1) how State and local governments have been consulted, (2) what the nature of the State and local comments was and (3) how the agency dealt with such comments.

#### 14. DEPARTMENT REGULATIONS AGENDA.

- a. Each initiating office prepares a semi-annual Regulations Report summarizing each proposed and each final regulation that office is considering for issuance and publication in the Federal Register during the succeeding 12 months or such longer period as may be anticipated. The Report is submitted to the Department Regulations Council, through the General Counsel, not later than the last working days of June and December each year and supplemented with an updating report not later than the last working days of March and September each year.
- b. The Report specifies for each proposed and final regulation being considered for issuance and publication:
  - (1) A title;

- (2) A description (including information on how any referenced document may be obtained);
- (3) The earliest expected date for a decision on whether to issue the proposed or final regulation;
- (4) The name and telephone number of a knowledgeable initiating office official who can provide additional information; and
- (5) Whether it is a significant or a nonsignificant regulation.

The Semi-Annual Regulations Report includes any final action taken since the last report.

c. For a significant regulation, the Report also briefly states:

- (1) Why it is considered significant;
- (2) The past and anticipated chronology of the development of the regulation;
- (3) The need for the regulation;
- (4) The legal basis for the action being taken; and
- (5) Whether a Regulatory Analysis is required.

d. For non-significant regulations issued routinely and frequently as part of an established body of technical requirements (such as the Federal Aviation Administration's Airspace Rules) to keep those requirements operationally current, the Report only states:

- (1) The general category of the regulations;
- (2) The identity of a contact office or official; and
- (3) An indication of the expected volume of issuance; individual regulations are not listed.

- e. The General Counsel's Office consolidates the initiating offices' Regulations Reports for the Council and from that consolidation prepares a semi-annual Department Regulations Agenda for publication in the Federal Register. Federal Register publication is for the stated purpose of sharing with interested members of the public the Department's preliminary expectations regarding its future regulatory actions and does not impose any binding obligation on the Department or initiating offices with regard to any specific item in the Agenda or preclude regulatory action on any unspecified item.

FOR THE SECRETARY OF TRANSPORTATION:



Robert L. Fairman  
Deputy Assistant Secretary  
for Administration

Mr. BROWN. Mr. Chairman, I'm going to ask that a chart be displayed for comment here by the represents of the various agencies.

Do you all have good vision down there? I can't read the chart from here, but I trust that all of you can. And I—did you distribute this to all of them? All right.

A copy of that chart is before the Members. And this is a flow chart illustrating the procedures that would be required in the regulatory process under the provisions of H.R. 9. And outlined in red are those points which might require judicial review.

And I know that many of you have commented on the possible delays that this legislation would require. And I'd like to have you refer to the chart and respond in just a general way, offer your comments as to what this would mean with regard to rulemaking in general. Could we do that?

And you don't need to belabor it. You know, it's quite clear what I'm trying to do here is show and tell that this constitutes a labyrinth of great complexity which would be very destructive of reasonable rulemaking. And you can just say yes, that's what it shows.

[The flow chart follows:]



Ms. GOLDMAN. Yes.

Mr. BROWN. You may elaborate on it, each of you. That includes you, Dr. Gibbons. You're not exempt. You're looking at the chart now, aren't you?

Mr. GIBBONS. It's quite a flow sheet, Mr. Brown.

Mr. BROWN. Well, I worked real hard on this. It took all my engineering background to do this.

Mr. GIBBONS. I think President Lincoln once said, a man, in his capacity, it was important not to say a foolish thing. Sometimes that meant he didn't have anything to say. So I would like to have a look at this, but it does, I think, represent a charting of the logic flow diagram of rulemaking under H.R. 9.

Mr. BROWN. All right.

Ms. GOLDMAN. Yes, to add to that, it is a bureaucratic maze, and we haven't had a chance to give this chart itself a detailed analysis, but I think our major concern overall is that we feel that the lack of any mention of judicial review would make this act reviewable under the Administrative Procedures Act, and that the certification requirements could also imply new opportunities for judicial review, in addition to the opportunities under our current statutes.

I think it's important for the committee to understand that so many of our decisions have such consequence economically and in other ways for the public that new opportunities for litigation, no matter how frivolous, will be utilized.

Mr. BROWN. Well, let me just say that we did not prepare this chart lightly. We think it is a correct reflection. We intend to use it on subsequent occasions, including when the bill comes to the Floor, if it does, in the present form. And I would like to request that after you have had a chance to study this in more detail, that you give me any additional comments that you might have with regard to whether it correctly represents the problems we face.

I'm going to ask just one additional question, purely for the purpose of elucidating information that I think we all ought to know. Reference was made during the testimony of the two Congressmen earlier, I think it was maybe in connection with the peanut butter example of imposing a risk standard of 10 to the minus 4 as compared with 10 to the minus 6.

One of you can explain in simple terms what the effect of the difference between a 10 to the minus 6 and a 10 to the minus 4 standards for carcinogenicity, for example, so all the Members of the committee can understand it.

Mr. GIBBONS. I may be simplistic, but 10 to the minus 6 is one in a million, and 10 to the minus 4 is one in 10,000.

Mr. BROWN. You are simplistic. What does that mean in terms of actual risk in the human population?

Ms. GOLDMAN. Let me—let me take a stab at it.

The one in a million has been widely misunderstood. What it's generally used as, is a number that many generally agree is indeed a negligible risk. Negligible, not meaning that that's something we need to be worried about, but meaning that's something we don't need to be worried about.

Mr. BROWN. Doesn't it mean one additional cancer death per million people?

Ms. GOLDMAN. Yes. And so if we have 270 million people in the country, if all were exposed to a one-in-a-million risk, that would be 270 additional cancer deaths, theoretically, that would result.

Mr. BROWN. And 10 to the minus 4 would be?

Ms. GOLDMAN. 10 to the minus 4 would then be 27,000 additional cancer deaths, rather than 270 additional cancer deaths.

Mr. BROWN. That's the point that I wanted to have you bring out. You brought it out. Thank you.

I have no further questions.

The CHAIRMAN. Thank you, Mr. Brown.

Mr. Weldon from Florida.

Mr. WELDON OF FLORIDA. I am sorry I missed the testimony of the other panel members, but I would just like to say for the record that in my campaigning for this office, I heard from a number of businessmen that the problem of Federal regulations, particularly environmental regulations, they were seriously impeding their ability to create new jobs. And jobs was a major concern during the campaign, in particular in light of the end of the Cold War and the loss of a tremendous number of defense jobs in Florida, this is a major concern.

We're looking at 200,000 jobs lost in our State. I know there are States that are even more adversely affected. I was recently very concerned about some EPA recommendations regarding the pulp and paper industry that were released. There are members of that industry that are very concerned about possible need to close down plants.

As the regulations are written, it will not be cost-effective for them to refit some of the plants. We're looking at possibly losing one or two plants in the State of Florida, tremendous adverse effect in the communities that have those plants.

And, Dr. Goldman, I'd be interested if your agency did a risk assessment on those particular regulations, and if you included in that risk assessment the adverse effect that it was going to have on the industry, the local economies that would be affected by it, and I'd be very interested to analyze your chart, Chairman—Ranking Minority Member Brown, in the future, to see if this is really an accurate representation.

I would like to comment that keeping a barrier between regulations that can be generated by the government and its impact on the public and the people is probably a very good thing, as we do have a tremendous amount of power in what we do here.

I'd like to hear Dr. Goldman's response to my question.

Ms. GOLDMAN. Yes, I think that too often in the past that people have behaved as if there is a conflict between the environment and economy, and too often we have carried out environmental regulation in an atmosphere of conflict instead of an atmosphere of cooperation.

And in the pulp and paper industry, the cluster rule, so-called, that we're working on, I think that is an example of where the—here at the EPA today, we're changing that. We have set up a Federal advisory committee to work with the industry and the other involved stakeholders on what this rule should look like. We have CEOs from the pulp and paper industry working with us. We have

done an extensive analysis of the costs. We've also done an extensive analysis of the benefits. And it is challenging to do that.

One of the problems in terms of analyzing the benefits is that although we can do a fairly good job, we think, with quantifying benefits in terms of preventing cancer risks, we're not very good at looking at risks to the ecology and some of the other risks that are very hard to monetize.

One thing that I think is going to be very important here is that the standard under our statute is that we must end up with whatever comes out of this whole process, the best available technology economically achievable. And so under the standard of the law, there should not be a result from this that is not economically achievable.

So I guess to conclude, I think what we're doing is what needs to be done. We need to move into a cooperative way of doing this. We need to look at the costs and the benefits. H.R. 9 is not that. What H.R. 9 would do is actually, for no logical reason, set up a number of complex new bureaucratic mechanisms that would not achieve the goal of doing what we're doing, which is bringing everybody together and actually working with the industry to come up with the right answer.

Mr. BROWN. Would the gentleman yield to me very briefly?

Mr. WELDON OF FLORIDA. Sure.

Mr. BROWN. It was not my intention in presenting this chart to raise unnecessary barriers, or to run a flimflam on you. You have a copy of the chart. I would like to have each Member of the committee look at it for themselves.

I think our goal is the same, to provide a more flexible, simpler, more cost effective regulatory system. And I don't want us in our haste to move something through here, to do something that's the opposite of what we both want. But if I have misstated anything, I will depend upon your good judgment to correct it.

Mr. WELDON OF FLORIDA. Thank you.

The CHAIRMAN. Thank you, Mr. Weldon.

Mr. Roemer.

Mr. Roemer has gone, all right. Mr. Rohrabacher.

Mr. ROHRABACHER. Thank you very much, Mr. Chairman.

I find it very amusing today because we seem to have the representatives of the bureaucracy complaining that Congress' new majority is trying to place the same restrictions on them that they have been placing on the American people for many, many years now. Government taxing, spending and regulating has been out of control. That's why the American people made a decision that a change is necessary.

And in terms of taxing and spending, we're trying to get that under control. Today is our effort, is focusing our effort to get the regulatory process under control. I mean, businesses today feel that there are arbitrary decisions being made by government regulators that affect not only the well-being of the business, but affect the well-being of the community and everybody who works for the business.

And it's there—many people believe that some of the arbitrary decision-making that's taking place out in regulation land is done in an arbitrary way. And to answer a question of Mr. Schultz, I

think it is something the public would like to see that, no, that your organization can't just make the decision that you think is right at the moment.

And I'm going to follow up with a question, give you a chance to get back on that. We are trying to say that good science and cost-benefit analysis and peer review are good things. This is a good part, a good formula to put into the system.

And I will tell you that sometimes hearing the suggestions from people—and I am sorry to make this sound political here, but coming from the Democratic party which has been the champion of more regulation, more taxing, more spending—and the complaint coming back from you folks that, oh, my goodness, this is going to make it bureaucratically more difficult, et cetera, sometimes I have to take that with a grain of salt.

Because it seems to me that you have had your chance and it—I, you know—and apparently the President uses the rhetoric of decreasing regulation, but he doesn't—but here we are trying to do something, and all of a sudden there is every—you know, they will always find a reason not to move forward on a solution or at least an alternative.

I will now—would like to turn to Mr. Schultz, about your specific peanut example. Because most of what I heard here today from the other witnesses were this could affect this and it could affect this and it could affect that. You know, when you say you used the word "could," instead of "absolutely would," you could say that about anything. I mean, that's just basically an off-handed way of dismissing something.

You said specifically that you would not be able to make that decision on the peanut decision if this bill passes. Are you trying to tell me that you could not reorganize your system, your structure, the bureaucracy there, the way you operate, to make it more efficient to set up a peer review process and a cost-benefit analysis and make sure that you're using good science? You couldn't put that into a system and make it efficient?

MR. SCHULTZ. The problem is that you have to get the information first before you can do a risk assessment. And sometimes the information just isn't there and sometimes takes time to get the information.

And in the peanut example, we have a rule. We say, if you're above 15 parts per billion or whatever it is, if you are above that, the peanuts are illegal. If you're below that, they're legal. And so the consequence of applying that rule to the industry is a very unhappy consequence.

And if you don't allow the Agency to exercise judgment in that situation based on the information it has, then I don't think you can—it can—

MR. ROHRBACHER. The essence—

MR. SCHULTZ. —make sensible decisions and take sensible actions.

MR. ROHRBACHER. As you're aware, Mr. Schultz, the essence of what we're trying to accomplish here is aimed at rulemaking, aimed at rulemaking. And then you don't have any disagreement if the rulemaking part of the process with the restrictions that we're trying to place on you, you're just talking about—

Mr. SCHULTZ. No, that's not right.

Mr. ROHRABACHER. Now you're hedging.

Mr. SCHULTZ. No, no, I said that's not right.

Mr. ROHRABACHER. I know.

Mr. SCHULTZ. I didn't mean to hedge.

Mr. ROHRABACHER. Okay. Well, the fact is, the one example you gave me was implementation. Now you are saying that in the rule-making side of this, that you also can't—

Mr. SCHULTZ. Well, I gave three examples. One of them was yellow number 5. When we did a product approval of a color additive, that's through rulemaking. Certain products that the Food and Drug Administration approves are done through regulations.

And we—even if you apply this to all our regulations, it's got problems. But I think the biggest problems and the most serious ones have to do with the fact that the bill was written to cover any assessment of risk, not just a regulation or rulemaking.

The CHAIRMAN. The time of the gentleman has expired.

Ms. McCarthy.

Ms. MCCARTHY. Thank you very much, Mr. Chairman.

I would like to pursue with Mr. Schultz the issue of the peer review, because in the legislation we are considering there is a section dealing with that. In your testimony, you indicated that you already do this, and that you create panels, the legislation calls for those panels to consist of independent and external experts.

Do you currently use outside experts when you are evaluating the regulations? And do you anticipate using these same people and could you also tell me who they are and are they academics or industry experts, just to give me a better sense of who you draw from and how they are compensated for their work?

Mr. SCHULTZ. First of all, when we use them, we use them very frequently for product approvals, particularly drug approvals, after the Agency has its—the staff has their initial decision. They will run it by a peer review panel.

In regulations, when we have a difficult issue that we think we can get help from a peer review panel, then we will refer it to the peer review panel. The panel is—the voting members are typically academics, but it can be others. There are conflict of interest rules, so industry members could not vote on a peer review panel, but the panel can accept input from the industry. And sometimes there are nonvoting members from consumer groups and industry. But the conflict of interest rules are, you know, make it—limit who can be on it.

And one big difference with this bill, of course, is that it really abandons those conflict of interest rules. The two problems we have with the approach in the bill are, one, the conflict of interest rules, and two, it would have us do peer review every time instead of having us do peer review when we have a difficult issue.

Ms. MCCARTHY. I'm glad you brought up that point, because that was what I wanted to discuss with you further. There is that new language on page 50 of the bill that states, in addition, the Director of the Office of Management and Budget shall order that peer review be provided for any major risk assessment or cost assessment that may have a significant impact on public policy decisions. That is on lines 8 through 12 on page 50.

And it would—your interpretation seems to indicate that we would be convening peer review panels to evaluate every regulation coming out of your agency.

Mr. SCHULTZ. Yes, we are a little unclear whether the threshold is every 25 million or 100 million, but whatever it is, we think there are times when it would be—it's just unnecessary, nobody would be asking for it. And it would be better to get the regulation out, it would be better for everybody.

Ms. MCCARTHY. Like other new Members on this panel, we fought hard to get here and our campaigns were not without discussions on risk assessment and how to make it better.

What is the ideal solution in your mind?

Mr. SCHULTZ. I don't know that I have an ideal solution, but I guess our view is risk assessment is very valuable. When you have a major regulation, we think it's useful and we do it and we think it's particularly valuable in setting agency priorities. In other words, have—the agencies ought to be going after the public health risks that are important, and the ones that aren't important ought to be lower, lower on the scale.

Ms. MCCARTHY. Well, I appreciate that setting of priorities, and I also want to assure you that your testimony, where you indicated the significant delays that might occur because of this new legislation, do give me pause. I didn't come here to make it worse. I came here to make it better.

Thank you for your testimony here today.

Mr. GIBBONS. Mr. Chairman, I could add a couple comments to that if it's appropriate. Could I add a couple comments?

The CHAIRMAN. The time of the gentlelady has not yet expired.

Ms. MCCARTHY. I would like to hear the gentleman's comments.

The CHAIRMAN. Her time is not yet expired.

Ms. MCCARTHY. Thank you, Mr. Chairman.

Mr. GIBBONS. We do want to be positive about this, because I think we are all—we all have the same ends in mind. It's a question in a sense not so much about the diagnosis, we've got some problems, but the treatment that is going to best work for the patient.

And I would state several things, it seems to me, that express what we think we ought to be doing here. One is, I believe the agencies ought to assure that they have evaluated the appropriateness of a regulatory solution; that the proposed action is based on the best, reasonably obtainable scientific, technical, economic information; that the benefits justify the costs.

We believe that legislation requiring risk and cost-benefit analyses should be limited in mandatory application to regulations having an annual effect on the economy of \$100 million or more. In fact, during I believe President Reagan's time, in which a dollar was worth a lot more, I think the hundred million level was indicated at that time.

We believe that legislative language could include provisions related to transparency and the explanation of the assumptions being made in the analysis, appropriate peer review, including requirements to develop a peer review plan, and the meaningful and appropriate comparison of risks.

We believe the legislation should include provisions for research necessary to improve the development and the implementation of risk analysis. As I said, garbage in is garbage out.

Three more points. One, legislation should include a provision stating that risk and cost-benefit analysis requirements should not be construed to amend, modify, alter, or supersede the requirements of other statutory provisions.

Secondly, that there should be a statement on commensurability, that is the amount of resources devoted to risk analysis and cost-benefit analysis should be commensurate with the significance of the regulatory decision being made.

And finally, that there should be a statement limiting judicial review. The objective of any legislation should be to improve the regulatory process, not create unproductive paper record requirements and further opportunities for litigation.

Ms. MCCARTHY. Mr. Chairman, may I inquire, is there any time remaining?

The CHAIRMAN. Your time has expired.

Ms. MCCARTHY. Thank you, Mr. Chairman.

The CHAIRMAN. I would ask unanimous consent, based upon the remarks of the gentleman, that a study by the Congressional Research Service on the possible impact of mandated risk analysis for regulations of various magnitudes, dealing with the \$100 million issue, be put in the record at this point.

[The information follows:]



Congressional Research Service • The Library of Congress • Washington, D.C. 20540

January 26, 1995

TO : Committee on Science  
Attn: Barry Beringer

FROM : Linda-Jo Schierow *[Signature]*  
Analyst in Environmental Policy  
Environment and Natural Resources Policy Division

SUBJECT: Possible Impact of Mandated Risk Analysis for Regulations of  
Various Magnitudes

This memorandum responds to your request for information about Federal regulations proposed or promulgated annually in each of four categories based on estimated annual economic impacts of more than \$1 million, \$25 million, \$50 million, or \$100 million. Specifically, you asked for the number and percentage of regulations in each category and the cost of conducting risk and cost analyses for such rules. As we discussed, information about regulatory actions expected to cost more or less than \$100 million annually has been compiled by the President's Office of Management and Budget (OMB) and by some Federal regulatory agencies. However, the potential economic impact of individual rules below the \$100 million threshold and the numbers of such rules within categories of more than \$50 million, \$25 million, or \$1 million have not been recorded, although a Congressional Budget Office (CBO) review of EPA rules provides some information for that agency.<sup>1</sup>

Information about the cost to agencies of risk and economic analysis also is unavailable, except for data collected by EPA and a CBO estimate for EPA regulations. The available information is summarized below.

#### NUMBERS OF FEDERAL REGULATIONS REVIEWED BY OMB

The attached table provides for each of the 20 Federal agencies most active in producing rules during the 1980s the numbers of regulations reviewed by OMB during 1990 and from Oct. 1, 1993 through Mar. 31, 1994, the six-month period following issuance of President Clinton's Executive Order 12866 on Federal Regulatory Review and Planning. It is important to note that this order

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<sup>1</sup> U.S. Congress. Congressional Budget Office. Letter to the Honorable John Conyers, Jr., Chairman of the Committee on Government Operations, U.S. House of Representatives, July 14, 1993.

requires OMB review only for "significant regulatory actions," which the order defines to include all final rules, proposed rules, notices of proposed rulemakings, and advanced notices of proposed rule making, but only if they are expected to: have an annual economic impact of \$100 million or more; adversely affect in a material way the economy, any sector of the economy, productivity, competition, jobs, or State, local, or tribal governments or communities; adversely affect the environment or public health or safety; create a serious inconsistency with an action taken or planned by another agency; alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients; or raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles for regulatory planning and review specified in the order. In 1990, OMB reviewed all "rules," as defined in President Reagan's Executive Order 12291 on Federal Regulation which includes final rules, proposed rules, and notices of proposed rule-making, but not advanced notices of proposed rule making. For more detailed information about OMB review of regulations, see CRS Report 94-961 ENR, *Risk Analysis and Cost-Benefit Analysis of Environmental Regulations*, pages 23-35.

The table also indicates the numbers of "rules" and "significant regulatory actions" that were expected to have an annual economic impact of more than \$100 million. All information in the table is from OMB.<sup>2</sup>

Based on information provided by EPA and a review of final rules published by EPA over the 4 years prior to July 1993, CBO found that EPA issues an average of about 170 rules annually of which 1 or 2 percent are major rules, that is, rules expected to have an economic impact of \$100 million or more. About 85 rules annually are "brief and concern fairly routine matters," according to CBO. CBO included in this category approval of State plans to implement Federal statutes and rules issuing or revoking tolerances for pesticide residues and food additives.

From 1981 to 1986, EPA reported that it issued about 1,000 regulations, including 18 major rules, 3 of which had statutory or court-imposed deadlines.<sup>3</sup>

## COST OF ANALYSIS

CBO estimated EPA costs to assess risks to health and the environment, implementation and compliance costs, and comparative risks for all final

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<sup>2</sup> U.S. Office of Management and Budget, Executive Office of the President. Regulatory Program of the U.S. Government, Apr. 1, 1991 - Mar. 31, 1992. Appendix IV. Washington, U.S. Govt. Print. Off. p. 704.

<sup>3</sup> Ibid. Report to the President on Implementation of Executive Order 12866. Appendix A, Tables 1 and 2. May 1, 1994. Unpublished. Unpaginated.

<sup>3</sup> U.S. EPA. Economic Studies Branch, Office of Policy Analysis. EPA's Use of Benefit-Cost Analysis 1981-1986. August 1987. Unpublished.

regulations. CBO assumed that no additional cost would be incurred by EPA for analyses of rules with estimated impacts greater than \$100 million annually, because EPA already conducts analyses on these rules. In addition, CBO assumed there would be no additional cost for the 85 regulations that concern routine matters. CBO estimated a total cost of about \$20 million to conduct analyses of the 80 to 90 remaining rules annually, with an estimated average cost per rule of \$200,000 to \$250,000, about one-third to one-half the cost of analyses conducted for rules in the \$100 million or more category.

EPA analyzed its costs for analyses of 12 major rules for which cost data were available that were conducted between 1981 and 1986.<sup>4</sup> The Agency concluded that its average cost per rule was \$685,000 and ranged from \$210,000 to \$2,380,000 per rule. Total expenditures for analysis of the 12 rules was \$8.1 million. However, only 6 of the 12 analyses were complete according to EPA, due in part to a lack of scientific and economic data.

I hope that you find this information helpful. Please call Linda Schierow at 7-7279 if you need further assistance.

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<sup>4</sup> Ibid.

**Total Numbers of Regulations Reviewed by OMB in Recent Years and Numbers of Such Regulations with Estimated Economic Impacts of More than \$100 Million for the 20 Federal Agencies Most Active in Producing Rules during the 1980s**

Department or Agency	All 1990	>\$100 million 1990	All 1993-1994 <sup>1</sup>	>\$100 million 1993-1994 <sup>1</sup>
Health and Human Services	354	14	126	8
Agriculture	333	17	94	13
Commerce	244	0	42	1
Transportation	242	11	44	15
Environ. Protection	173	21	53	16
Interior	102	3	34	1
Veterans' Affairs	87	0	21	0
Justice	78	0	15	0
Education	66	0	25	2
Treasury	64	1	3	2
Housing & Urban Development	63	1	25	4
Labor	58	12	2	1
Personnel Management	52	0	17	0
General Services	35	0	9	0
Small Business	35	2	16	3
Emergency Management	25	0	2	0
Energy	14	0	6	1
Archives and Records	13	0	1	0
Aeronautics and Space	9	0	4	0
Defense	8	0	8	0
<b>TOTAL</b>	<b>2055</b>	<b>82</b>	<b>547</b>	<b>67</b>

<sup>1</sup> These numbers are for Oct. 1, 1993 through Mar. 31, 1994, the six-month period after President Clinton issued Executive Order 12866 on Regulatory Planning and Review. This order requires OMB review only of "significant regulatory actions". Prior to Oct. 1, 1993, OMB reviewed all regulatory actions.

The CHAIRMAN. Mr. Minge is next.

Mr. MINGE. I have a couple of specific questions. One is addressed to you, Mr. Collins. You talked about a certain beetle that was infesting the north central region of the country, and indicated that you would not be able to promptly respond in USDA if this particular legislation or bill was enacted.

And I'm wondering, wouldn't the emergency exemption that exists in the bill be adequate to deal with situations like that?

Mr. COLLINS. Well, that's a good question. The problem with the Department of Agriculture's programs and what we do is that we deal with threats. And we don't call them emergencies until we have to go to another level of response.

Many of the plant pests or animal diseases that we deal with, we detect through traps or we detect through some kind of a monitoring system. We do risk assessments all along the way to determine what the monitoring system should be, where traps should be set, and so on. And as the level of the possible risk escalates, that calls into play different responses.

Mr. MINGE. So the word emergency is a term of art?

Mr. COLLINS. The word emergency is more than a term of art. I mean, we have triggers that determine emergency, but when you trigger an emergency, it brings into play a whole new level of risk communication. It brings into play a whole different higher level of costs. And it also involves—causes us to go out and deal with the public and inform the public that an emergency is occurring.

Mr. MINGE. So what is the definition of an emergency as you would understand it for the purposes of this legislation?

Mr. COLLINS. I don't know what the definition of an emergency is for this legislation, and that's a problem. Because I think if we have a plant pest, for example, that we detect, and we are monitoring, now under the current situation, we can respond quickly with a risk assessment. If it appears that the risk assessment is going to take a long time and we're going to be unable to act over that period of time, it may cause the Agency to want to declare an emergency, to avoid this legislation.

Mr. MINGE. So a definition of the term emergency that was fairly broad to enable you to respond to the example that you gave, would clean up part of the problem with the legislation, at least that part of it?

Mr. COLLINS. Well, it may clean up technically that part of the legislation, but it calls into question our ability to deal with the public. I mean, is it good public policy for us to be going around and declaring emergencies more frequently than necessary?

Mr. MINGE. A second question I would like to address to each of you is, who bears the cost of peer review in your agency, the academics that do this, your agency, the industry, or whom? And I will start with you, Dr. Goldman.

Ms. GOLDMAN. Yes. The way that we conduct peer review at the EPA is various levels, ranging from paper peer reviews, where our documents are sent to outside scientists who do the review and give us paper reviews, to assembly of panels of peer reviewers to use of our Science Advisory Board. And we currently involve some 200 scientists and academics outside of the agency.

We do bear the costs. The Agency pays out of our budget. It's a part of the costs of doing any new science effort, to also appropriately budget for the peer review.

Mr. MINGE. Mr. Collins, USDA, who bears the cost of peer review?

Mr. COLLINS. Mr. Minge, peer review is not instituted formally at the Department of Agriculture yet. Our risk assessment legislation that was enacted four months ago has mandated us to develop a set of risk assessment principles and practices and we are now establishing our peer review principles right now.

Mr. MINGE. Mr. Schultz?

Mr. SCHULTZ. The Agency bears the costs. The members of the panel are paid a per diem at government rates.

Mr. MINGE. So that you are not using industry in the course of, say, this yellow dye and so on, as a way of raising funds to pay for peer review?

Mr. SCHULTZ. No. See, on an issue like this, that wouldn't even go to peer review under our current practice, because there is no difficult issue that would merit it.

Mr. MINGE. In the opening comments that you made, Mr. Gibbons, you indicated that this is a feed bag for lawyers, lobbyists and bureaucrats. I'm wondering, could we add the academics to this list? It looks to me like peer review would become a very popular process and we would include thousands of university and research institute folks in this whole process.

Mr. GIBBONS. I'm very sympathetic with your point. Let's add them to the list.

Mr. MINGE. Okay. I have another concern I'd like it address to you, Mr. Collins. You have indicated that the U.S. Department of Agriculture is currently trying to comply with the reorganization legislation that sets up a risk assessment process.

Is the risk assessment process as set up in that bill, in that legislation, different than the risk assessment here? And if so, how? Could you just quickly identify the highlights of the difference?

Mr. COLLINS. Yes, sir, it is different. It's quite a bit different. First of all, the objective of the statute that we're working under invokes risk assessment for activities that are primarily directed at human health, human safety in the environment.

The word "primarily" is important, because at the Department of Agriculture we do an awful lot of things such as our annual production adjustment program for corn or wheat, which is intended to control price and affect prices and has an indirect effect on the environment. So a number of those programs are filtered out by the opening charge of the statute. So it is tailored to our programs at the Department of Agriculture.

Secondly, it has a fairly broad but important charge that we are to use reasonably obtainable and sound scientific technical and economic data, without going beyond that, without being very prescriptive. It has provisions for comparisons among risks, but it doesn't ask us to compare risks that are outside of the scope of the Department of Agriculture or unmeaningful.

It asks us to compare risks that are regulated by the agency that is promulgating the rule. It asks us to estimate qualitative and quantitative benefits, but it says that if we cannot establish quan-

titative benefits, then we are required to provide an explanation as to why we cannot establish quantitative benefits.

A very important difference is that our provisions are specifically excluded from judicial review, which is a major difference with H.R. 9. Another important difference is that the rules that are affected have to have an annual economic effect of \$100 million or more, not \$25 million or more. And lastly, our provision does not mandate peer review as H.R. 9 does.

Mr. MINGE. Then I just—is there any time left?

The CHAIRMAN. The time of the gentleman has expired.

Mr. MINGE. Thank you.

The CHAIRMAN. We now go to Ms. Rivers.

Ms. RIVERS. Thank you, Mr. Chair. I have a couple of questions.

The first one, I guess I would direct this to Dr. Goldman, though any of you could answer it. Who ultimately has authority for all of your agencies? Congress? The White House?

Ms. GOLDMAN. Well, ultimately our statutory authorities come from Congress, and it's the responsibility of the President to make sure that those are carried through.

Ms. RIVERS. Okay. So in effect the President has a right to oversee what you have done, how you have done it, and the effect that it's having?

Ms. GOLDMAN. Well, yes. The President and the White House carries this out, kind of set the rules of the game for how the executive branch does its business.

Mr. SCHULTZ. FDA is a little different. The statute gives the authority to the Secretary of the Department of Health and Human Services. And while the White House and OMB, so on, have input and review things, it's the Secretary who has the ultimate authority. And it's delegated to the Commissioner of FDA.

Ms. RIVERS. So for all of you, the authority is vested in the executive branch, which of course until 1993, January 1, was for 12 years at least run by the Republican Party. And so it's important, I felt I needed to point that out, given Mr. Rohrabacher's comments earlier.

Secondly, I need to know from Ms. Goldman, as you look at your agency today, and you look at the chart, and I know you haven't had a chance to review it carefully, what do you see happening to your legal budget?

Ms. GOLDMAN. Well, we've only begun to look at it, but we do believe that this will be a full employment act for attorneys, that it will create many more opportunities for litigation. Whether or not that litigation will be won is open to question, but will certainly then create delays in needed decisions.

Ms. RIVERS. Okay, thank you.

Mr. Schultz, the question I have for you, someone suggested that this bill was going to produce paralysis by analysis, and that everything would stop. And sort of the gold standard for intrusive and lengthy regulatory procedure has been held by the FDA for good or for bad.

How does the FDA's process that is currently being attacked so strongly compare to this one?

Mr. SCHULTZ. We haven't done a chart like that, but, I mean, I think it's considerably simpler. But I do think—I mean, even for

product approvals, which is where—I mean, that's where we're really, you know, we really are working on making improvements, the time it takes to approve drugs and devices. Putting this on top of it is going to make our job even harder than it already is.

Ms. RIVERS. And the last thing I wanted to ask you, Mr. Schultz, is there is an article, there was an article that ran in The Washington Post today, actually, I don't know if you had a chance to see it, that contrasts United States, Britain, Germany and France and the need to pull unsafe drugs off the market and shows a tremendous discrepancy between the four countries. During the time that this was charted, between 1970 and 1992, 56 drugs were removed from the market in those four countries, 31 in France, 30 in Germany, 23 in Britain, but only 9 in the United States. Why is that?

Mr. SCHULTZ. Well, I've looked at the study that that article is about, and the main reason is that our approval process is such that the drugs don't get on the market here in the first place so we don't have to take them off.

Now, we've been criticized for taking too long, but we have a—we have made great strides in the Clinton administration in the last couple years, and I think the drug companies are quite happy with it. I mean, we have to be careful as we go through these changes that we're not making it harder to do things that all of us want us to do more efficiently.

Ms. RIVERS. Okay. Thank you very much.

Thank you, Mr. Chair.

The CHAIRMAN. Thank you, Ms. Rivers.

Mr. Ehlers.

Mr. EHLERS. Thank you, Mr. Chairman. My question can be reasonably brief, since it follows up somewhat on Congresswoman McCarthy's earlier comments. And I appreciate Dr. Gibbons' response to that.

At the first hearing we had on this I was one of the few who registered some concerns and warned the panelists and my colleagues not to regard risk assessment as a panacea, and also warned against excessive judicial reactions resulting from implementation of the bill. And it's always nice to have someone agree with part of what I say.

But I have to express disappointment with the panel before us because of all the nay saying. I didn't realize that this bill was going to make the sky fall and the earth stop turning and so forth. I was hoping for a more positive approach and that's why I particularly appreciate your comments, John, in response to Ms. McCarthy's questions.

What we're trying to do is simply ensure that we have fair and reasonable assessments, that the process is simplified, and above all, that the assessments, the procedures used and the results obtained, are consistent across all the departments, in other words, a good relative ranking from one department to another, and that the benefits are somehow commensurate with the costs and the effort that goes into creating them.

Now, obviously this bill is an attempt to do that, and you're all saying it's wrong. I would certainly challenge you to come up with specifics of how you would write a bill to accomplish those objec-

tives which are pretty clearly outlined, and improve your processes to achieve those objectives.

If this doesn't work, what will work? And I'd like to have you get that back to the committee as soon as possible.

I have very little patience with simply trying to preserve what we have because you're used to it. I have a lot of patience in dealing with someone who says, hey, our process is not very good, we can improve it and meet your objectives and do it better than the plan you have developed.

Mr. GIBBONS. I appreciate those comments, Congressman.

I do feel that we are not arguing for status quo because we've been changing pretty rapidly in the administration. And perhaps it's not as well described or earlier described as we should have about what was going on, but I'm certainly prepared, as I know my colleagues are, to, beginning this afternoon, to, for instance, designate a team from the administration to work with a bipartisan portion of this committee and see if we can't work together, using our collective experience, to improve the legislation, see if we can't get a better merging here.

Ms. GOLDMAN. I should add—I should add that in the last Congress, there were a number of efforts on the part of the administration or that the administration supported to change the process. Certainly the President signed the agriculture bill that set up the new process at the Department of Agriculture.

We also worked very hard to change the way that we look at risks, costs, benefits within Superfund, within our drinking water programs, within our pesticide programs, where we attempted to change the process for how we set tolerances for pesticide on foods and the Clean Water Act.

And those efforts unfortunately have not all come to fruition yet, but I hope that is a demonstration to you that we are serious about these kinds of changes. This isn't just rhetoric coming from our side in the administration. We worked very hard to try to accomplish these kinds of changes.

Mr. EHLERS. Thank you very much.

Mr. Chairman, I would certainly be interested in seeing the product you produce, but we will measure it against the criteria that I just listed and also a few of those that Dr. Gibbons listed a moment ago.

Thank you very much. I yield back my time.

The CHAIRMAN. Thank you, Mr. Ehlers.

Mr. Ward.

Mr. WARD. Yes, before I begin, if I could ask unanimous consent to include in the record an article from today's Washington Post that was referred to by Ms. Rivers.

The CHAIRMAN. Without objection.

[The information follows:]

# Study Says U.S. Has Better Barrier to Bad Drugs Than Europe

By John Schwartz  
Washington Post Staff Writer

The American system of drug regulation works better than several European nations' programs at preventing dangerous drugs from reaching consumers, a new study released yesterday concluded.

The Public Citizen Health Research Group compared the number of drugs that had to be taken off the market after approval in four countries because of dangerous side effects. Of 56 drugs withdrawn from the market between 1970 and 1992, 31 were withdrawn in France, 30 in Germany, 23 in the United Kingdom and nine in the United States. (In several cases, the same drug was withdrawn in more than one country.) Of the nine drugs withdrawn from the U.S. market, three of the manufacturers later pleaded guilty to

criminal charges of having withheld evidence of drug risks from regulators.

The report shows that America's drug regulatory system "protects people from a large number of products that kill and injure people in other countries," said Sidney M. Wolfe, executive director of the Health Research Group. "It really is 'advantage—U.S.' by far." Wolfe's organization long has been critical of the Food and Drug Administration's drug approval process, which it contends lets too many hazardous drugs and devices onto the market.

"By having lower safety and efficacy standards, other countries are making gunners pigs out of their population," Wolfe said. By watching the performance of newly marketed drugs in other countries, FDA officials often learn the unforeseen side effects of new medications, he added.

The FDA often has been criticized by companies that make drugs and medical devices for its slowness in approving new products, which they contend hurts American competitiveness and ill serves patients. In recent months, support for anti-FDA legislation has grown as Republicans took control of both chambers of Congress. On Wednesday, Rep. Thomas J. Bliley Jr. (R-Va.), chairman of the Commerce Committee, which oversees the agency, criticized the FDA in a speech to the National Committee for Quality Health Care.

"It just breaks my heart when I think of American citizens having to go to Switzerland or Mexico to get the drugs and devices they need to stay alive because the Washington bureaucracy won't approve them," he said. "And I promise you this session there will be—repeat, there will be—reforms in the way that the

Food and Drug Administration does business."

Several conservative think tanks also have announced that they are looking at ways to reform or even restructure the agency. Sam Kasman, general counsel for the Competitive Enterprise Institute, said Wolfe's study was misleading. "If you did not approve any drugs, you would not have any drug recalls. You've got to compare the damage of what was done by any drug's recall to the therapeutic advantage of those drugs that were released earlier in Europe than they were here," Kasman said.

Steve Berchem, a spokesman for the Pharmaceutical Research and Manufacturers Association, said, "We feel strongly that we need to have high safety standards at the FDA. There's no doubt that there need to be improvements." Berchem noted that the agency only approved

one new drug produced through biotechnology last year, and said that products such as a vaccine for hepatitis A, which is available in 40 countries, need not be held up in the U.S. regulatory process.

Several of the drugs cited in the study were never approved for the U.S. market. Clometacin, an anti-inflammatory drug, was linked to 130 reports of liver damage—including nine deaths—in France. The anti-inflammatory drug Indomethacin-R, marketed and later withdrawn in Britain and Germany, was linked to 717 reports of adverse side effects, including 36 deaths. Terodiline, a treatment for urinary incontinence, was linked to 69 reports of irregular heart rhythm in Britain and Germany, including 14 deaths.

FDA spokesman Jim O'Hara welcomed the results of the Public Citizen study. "The United States sets

## DAUGHTER MEDICINE

Between 1970 and 1992, 56 drugs were removed from the market in France, Germany, Britain or the United States because of safety problems.

DRUGS MARKETING AND  
LATER WITHDRAWN  
1970-92

COUNTRY	1970-92
France	31
Germany	30
Britain	23
United States	9

NOTE: Some of the 56 drugs were withdrawn in more than one country.

SOURCE: Public Citizen Health Research Group

THE WASHINGTON POST

the gold standard for safety and efficacy of drugs in many ways, and thus is one more sign of that."

THE WASHINGTON POST  
February 3, 1995

Mr. WARD. Dr. Goldman, you referred to parts of this as maybe the full employment act for attorneys. At the risk of offending my wife who is an attorney, let me ask each of you, please, to comment on how you feel we come out when science and law meet.

Certainly the law is an inexact science, but also scientists often have the tendency to have to change their views as a result of what the lawyers or the judicial process tell them. If each of you could react to that, and Dr. Goldman could go first.

Ms. GOLDMAN. I will start.

I think one of the important things for the committee to look at is the way that this bill would be covered under the Administrative Procedures Act, which not only can create a challenge because an agency has been arbitrary and capricious, but also if we have acted not in accordance to the law.

And there are places within this bill where there are lists of activities that should be carried out, that shall be carried out in assessing a risk, or that shall be in our guidance, that are not applicable to all the assessments that we do today. These lists appear to be quite applicable to how today we look at cancer risks, but not noncancer health risks. And that may not be the way we do a cancer risk assessment in the future as well. And so we have to be careful about them.

Also, these lists include things that are sometimes relevant for cancer assessment, like doing a study of a comparative study between species, inter species physiological studies. That's a very rare thing. Someone can do a Ph.D. dissertation on some of those studies for some of the compounds that we look at.

And so while I would say we should look at those studies if they have been presented to us and if they are pertinent and relevant, there's nothing in here that applies of relevancy determination or rule of reason determination. Everywhere it says shall, shall, shall. And that's my concern.

Mr. GIBBONS. I could add just a moment. Victor Hugo once said that science has the first word on everything and the last word on nothing. And I think that aptly reflects the fact that science does, as it were, provide the foundation, the groundwork of the facts, and then the policymakers must do with that what they may.

And what they may includes not only recognition of the facts, but also the economic considerations, social and ethical consideration and the like. That comes to the lawmakers, such as yourselves. When we speak of lawyers here, we were speaking of litigation.

And as I looked at the chart that is on the poster, I note that in the lower left it describes with an asterisk, all those places which are identifiable as a place where a litigator can come in and block the process or make it more expensive. I differ, therefore, in talking about lawyers, and I come from a family of them, and legislators, who are the citizen governors that have to make those decisions ultimately.

Mr. COLLINS. I would only add to that, that Mr. Gibbons' few views of the law, the congressional view and the litigious view, has a great effect on us. Obviously the rules that we implement at the Department of Agriculture are the product of an action by the Congress. As we implement those, we are very concerned that a lot of

what we do is not directly amenable to some of the prescriptions that are in here.

When we talk about scaling effects from animals to humans or dose and response, we have large programs that are intended to idle certain parts of cropland so that we can generate wildlife habitat. The hazard is the farming of the soil and the risk is what happens to bird populations. And these are different kinds of assessments. And if we are open to litigation because we didn't follow part of the cookbook, we're concerned about that.

And I don't have to tell you that when it comes to something like the Forest Service, the Department of Agriculture at any one time has thousands of pieces of litigation imposed against us. So the legal costs and consequences are a concern.

Mr. SCHULTZ. Currently the basic principle for judicial review of scientific agency decisions is you get review but it's a very limited kind of review. And I think that's appropriate, the Agency get a fair amount of deference.

The problem, when you get into a bill with this kind of detail on these procedures, particularly the ones here, is that it's an invitation to lawyers, and this is industry lawyers who don't like a regulation, or public interest lawyers saying we want to streamline our procedures for drugs, and public interest lawyers don't like it.

When you tell the Agency, for example, that it must consider alternatives, and say the Agency does it and it does consider alternatives, it's still an invitation for somebody to go to court and say, well, here is an alternative you didn't consider. And so you really—you really make the Agency vulnerable in terms of its ability—its ability to act.

We were sitting around the other day talking, there were some people from the General Counsel's Office, about where there might be cuts in the Agency. And the lawyer from the General Counsel's Office piped up and said, "I'm not worried about our office, because they will be very busy".

Mr. WARD. Can I just make one more comment to the Chair?

I want to thank you for allowing us to ask our questions as we are here at the time the gavel comes down. I'm the third freshman here in a row who's gotten to ask a question. At least for the next four, six, or eight years, I appreciate that.

The CHAIRMAN. I thank the gentleman. We are trying to assure that Members do come and attend the hearings, and listen to the witnesses before they ask the questions. And this is one method of assuring that maybe that helps happen. So I thank the gentleman for that.

Mr. McHale.

Mr. MCHALE. Thank you, Mr. Chairman.

Mr. Chairman, I have a very strong interest in the next panel of witnesses. A special friend and constituent will be one of the witnesses appearing before our committee.

And so in the interest of time, I will yield back my time and reserve my comments until a later point.

The CHAIRMAN. The Chair is most grateful to the gentleman.

Ms. Jackson Lee.

Ms. JACKSON LEE. Thank you very much, Mr. Chairman.

And likewise, to the Ranking Member Brown and to the Chairman, it is very, very much appreciated for this spread of witnesses on an issue that no matter what side of the aisle you come from impacts your constituents. I appreciate the presentations that were made earlier this month, and clearly have an interest in this question of risk assessment from twofold.

One of course, I always mentioned NASA in our community, in our city, and the very important focus of some of the work that they do, short of the excitement of going into space on a regular basis. But also, in Houston in particular, I have had the opportunity to interact with the community of biotechnology researchers. And that is an area that we as a city, in light of the Texas Medical Center, and several of our institutions, are certainly very much inclined to be involved in. And so I want to offer again the fact that this impacts all of us.

At the same time, I come from a constituency that speaks certainly very strongly about environmental cleanups and clean water and clean air and of course I know this issue stretches beyond those concepts. But I do have a slight bit of confusion on the issue, and I think it would be important for us to try to narrow maybe the question.

We have heard the Superfund, for example, and we certainly have had our experience with that in Houston, utilized by several witnesses, as an example of a site being cleaned up in New England, for example. And at that time, soil cleanup was to be such that it could be ingested by children, to that level. And of course many of us may have had that experience, but we would ask that our children not do that, eat soil, call it mud pies. But it is easy to see that a requirement for that level of cleanup may be in some circumstances ridiculous.

However, it is unclear to me how the guidelines for risk assessment in this bill will alleviate that kind of problem. If the Superfund statute still requires a level of cleanup for all Superfund sites that would allow the sites to be used as school yards, playgrounds and residences, does a more extensive risk assessment provide us more flexibility in setting a level of cleanup?

And I guess my question is, if the legislation in the existing statute, if this legislation changes an existing statute, then what will be the purpose of the savings provision that is on page 37 of the bill, meaning that are we now doing something that is irrelevant or is this in fact meant to change existing law? And do we really want to do that?

Or do we want to, as Dr. Goldman had indicated, come at this not from a conflicting position but really from a position of trying to work it out?

Superfund cleanups are positive. Certainly the extreme of how clean you should make the sites and for what purposes you are cleaning them should be a question to be asked. But certainly are we trying to eliminate that kind of cleanup, and does this legislation do so?

Dr. Goldman, if you could, I would appreciate it.

Ms. GOLDMAN. Well, I would agree with much of what you had to say about Superfund and about the need for change in how the Superfund program is conducted.

Last year, there was a major effort to do a Superfund reauthorization that would have accomplished really the two goals that you have laid out here, one being that we are more sensible about the risks and be flexible about cleaning sites down to an appropriate level, depending on what we want to use the site for.

And it is absurd to say that every site would be used as a playground in the future. Some of these will continue to be industrial sites. That really needs to be fixed. The other thing that we wanted to do is to decrease the amount of transaction costs in the Superfund program. Something like 40 out of every hundred dollars spent on Superfund is wasted in needless transaction costs. And I am afraid that what we're actually looking at here with H.R. 9 is not a process that will fix Superfund, but rather will build in more transaction costs, more opportunities for delay, more opportunities for litigation, and add to the current standards that we operate under the Superfund law some new performance standards for the Agency, new things that we will have to do to meet every jot and tittle of H.R. 9.

And so I would urge you to look carefully at that. Because I think that this is an example where a focused and targeted approach can fix a problem, come up with a common sense solution, whereas an approach like this, although perhaps well-intentioned, will actually complicate and make the process more bureaucratic.

Ms. JACKSON LEE. I quickly follow up with Mr. Gibbons.

The CHAIRMAN. Your time has expired.

Ms. JACKSON LEE. Even as I ask the question.

The CHAIRMAN. The time is expired. I allowed the witness to finish, but the time is expired.

Ms. JACKSON LEE. I will follow up with you. Thank you very much.

The CHAIRMAN. Thank you.

Ms. Lofgren is not here.

Mr. Luther.

Mr. LUTHER. Thank you, Mr. Chair.

First of all, I did want to ask a question on the prospective or retroactive application of the legislation. But, Mr. Chair, if I could just address it to you, because I believe you have indicated that you may be offering an amendment to limit the legislation to a prospective application. And if that is the case, I would not inquire in that area. Otherwise, I would like comments on that part of the legislation.

The CHAIRMAN. Well, I indicated that one of the options certainly would be to make this legislation prospective. And it's certainly one of the things—we are in the process of trying to work with some of the other committees that have jurisdiction on this, to try to modify some sections of the bill to deal with some of the problems we've heard about today, in addition to dealing with some of the issues of trying to go back and retrospectively handle some of these things. I think we're going to be able to satisfy some of that in some of the work that is being done.

I'm most grateful to hear Mr. Gibbons indicate that the administration would be willing to work with us in that regard. We want to try to deal with some of these things. I don't believe that we are going to be able to deal with some of the underlying philosophical

concerns on this that simply say everything we've been doing has been wonderful and we want to keep doing it. I think we're going to have some problems with that.

Mr. LUTHER. Okay. Thank you, Mr. Chair.

In the interest of time then, I would like to just echo what Mr. Ehlers indicated, and Ms. McCarthy. What I'd like to see is a workable, common sense approach to looking at prospective application, and then perhaps going back and looking at a few selected programs where perhaps there has been a lack of adequate scientific information, perhaps there have been claims that not enough objectivity has been involved in the process, and aggressive program, something that's very aggressive.

And I know, coming from State government, that sometimes with agencies and people you work with within your agencies, that's oftentimes difficult. But I think that if we could put together some kind of an aggressive approach like that, and I'd like to hear from you, quite frankly, it seems to me that would be the common sense way to approach this, rather than to create some of the problems that I would see coming out of the bill in the form that it's currently written.

So that would be my thought, to follow up on the positive approach that they indicated that they were receptive to.

Mr. BROWN. Would the gentleman yield to me very briefly?

Mr. LUTHER. Yes.

Mr. BROWN. I share the gentleman's view about the need to develop a positive approach. I would point out in response to what the Chairman said, that we are not interested in protecting the status quo.

This committee last year, as he knows, voted on a risk bill which did not get enacted. We are anxious to move on this. And as long as he's consulting with the other committees, I would like to suggest that he consult with the Minority on this committee. We would love to be cooperative.

The CHAIRMAN. Well, we would look forward to doing that. And if the gentleman will yield, I would simply say I want to go back to the point, I just asked staff about any potentials for retrospectivity in the bill.

It's my understanding the only thing that we are contemplating at all that would have any retrospective applicability would be an ability of industry to petition the Agency if new evidence accrued about old regulations. They would have the ability to petition on the basis of new evidence under what we now have. But it is not—we do not intend for this to go back and redo everything that has been done.

I thank the gentleman.

Mr. Graham.

Mr. GRAHAM. Thank you, Mr. Chairman.

I guess this is to all the panelists. Could you, if possible, provide me a summary of the reform measures since 1992 that the administration has engaged in to improve risk assessment? Give me a list of legislative initiatives that has come out of the administration, so that I could compare those with what we're trying to do.

Mr. GIBBONS. We would be happy to supply that to the committee.

Mr. GRAHAM. Okay, thank you.

[No additional information submitted.]

Mr. GRAHAM. We've been talking a lot about lawyers. I happen to be a lawyer, so I guess everybody hates lawyers now, the Republicans and Democrats. One thing that I've noted is that the Vice President's Reinventing Government, no one's complained to me about that. I haven't had one person come to my office and say the Vice President is going too far too quick.

Everybody is complaining about what we're trying to do, except the American business people and Joe Six Pack. The only people that complain to me about the Contract With America are the people here in Washington, so I am encouraged.

Can you—can you comment on a situation happening in my hometown? Maybe is to the EPA. It's a town of 2,000 people. And this may have been a Republican problem, I don't know. It's a water testing mandate that we had to go test the water for contaminants not indigenous to South Carolina, that cost us \$16,000.

How does such a thing happen? And what can we do to prevent it in the future?

Ms. GOLDMAN. We share with you concerns about how the testing requirements for drinking water are carried out. In the current drinking water law, there is a provision that if a community has financial problems with meeting the standard and if there are indeed contaminants that they're testing for that never appeared in that community, never been used in that community, there is an exemption process that's available for communities to use in order to change the requirement. But what has been apparent is that many communities have not chosen to use this process.

One of the things that we tried to do in the reauthorization process last year for the safe Drinking Water Act is to improve that process, because obviously if our customers, the communities, aren't using the process, the process needs to be fixed. It needs to be a better process.

The other thing that we've tried to do in other cases where there are other provisions that are expensive and hard for small communities to meet, is to make funding available, a revolving loan fund available for small communities to be able to upgrade their systems. Because sometimes when smaller water systems can be combined, then actually they can be in a better position to be able to provide the kind of safe drinking water that the people in their communities want to drink.

Mr. GRAHAM. Thank you. And I look forward to talking to you about that. Thank you.

I yield back the balance of my time, Mr. Chairman.

The CHAIRMAN. I thank the gentleman very much.

Ms. Lofgren has come back in the room and she would be next.

Ms. LOFGREN. Thank you, Mr. Chairman.

You know, I—we hear from our various constituents frustration sometimes about the regulatory load and certainly I do from time to time as well. And yet we all know that there is a benefit at times to regulations and to caution.

I know that the parents of America who did not take thalidomide were happy that the FDA was there and it's worth keeping that benefit in mind. Still, in the area of pharmaceuticals, there is con-

cern, and I think there is some justifiable concern, about the very extraordinary period of time it sometimes takes to qualify drugs for use in this country.

I am wondering, Mr. Schultz, thinking about an example, say clozapine, that was permitted for use in this country and there was only I think a year left on the patent by the time it was actually approved for use in America. Now that was under the Reagan administration, if my memory serves me well.

How would clozapine, a clozapine-type situation, where it was in use successfully in Europe for so many years, be treated under your agency now? And would you be able to contrast the approach to use of that drug with this chart in this proposal?

Mr. SCHULTZ. Let me tell you the two things we are doing in terms of drug approvals that are very significant. The first one is, it's most important to get the drugs that are significant advance over what's already available on the market reviewed and approved very quickly.

And we have a program to do that. And those drugs now typically get approved in less than a year. There's some AIDS drugs that have been reviewed in four or five months. And we feel like we're doing very well there.

Secondly, in 1992, Congress passed a user fee program. This was an agreement between the Agency and the industry and ultimately Congress where the industry gives the Agency user fees. Those fees are additive, so they give the Agency additional resources without coming from tax dollars. And the Agency then uses those resources so it can review drug applications. Because, after all, even a company that just has a drug that's a duplicate, has a right to get it approved quickly.

And under that program, we have committed, once it's fully implemented, to review all drugs within 12 months, and life-saving drugs within six months. The industry would be delighted with that. The American people would be delighted with it.

We think we are on the road and we are very concerned about something such as this bill, if it's really intended to have us go through a different kind of risk assessment or cost-benefit analysis for drugs. There really hasn't been a complaint—there have been complaints about delays, but there haven't been complaints about how we assess the risks or, you know, the procedures in this bill have never been suggested that I know of by the industry as an improvement in our process.

Ms. LOFGREN. Speaking of the accelerated process for medication that may be effective in AIDS cases, how would the regulatory scheme before us either assist or deter approval of drugs in those instances?

Mr. SCHULTZ. The concern that we have, and there are parts of this bill that, you know, are not totally clear, but the concern that we have is that it would require us to go through additional steps, both when we approve the drug for investigation and when we approve it for use.

A lot of the time that's taken—the Agency has taken more time than it should have in the past and we're doing better, but a lot of the time is taken to test the product, and it's very important to give the Agency, allow the Agency to retain the ability that it now

has when a company comes in and says it wants to test the product, to look at that application very quickly and let the test begin. And we're concerned that this bill would make that more live.

Ms. LOFGREN. Thinking about HIV, I noted that just a couple of weeks ago that a new strain of HIV has shown up in the blood supply in Los Angeles. I don't know what response the Agency is making with our blood supply in testing to that new find.

But could you advise us what response, if you felt that was a threat, you would take now under the current regulatory scheme and structure, and how that would be altered by the proposal before us?

Mr. SCHULTZ. Well, this is what I tried to talk about in my testimony. I think the American public and everybody agrees that the controls on blood should be very tight and very careful, and we should err on the side of overdoing it.

And the concern that I have is this—the bill, if it really intends to make us do a formal risk assessment before we take action, could impede our ability to act quickly when we know there's a problem and we know what it is.

Ms. LOFGREN. Thank you, Mr. Chairman.

The CHAIRMAN. The time of the gentlelady has expired.

Mr. Geren.

Mr. GEREN. Thank you, Mr. Chairman. I'm going to be very brief. I want to see the next panel before the snow falls.

But I want to echo the comments of Mr. Ehlers and I'd like just to hear from you all, the pendulum swings, and in the world of politics and for a long time we did very little to protect ourselves against various risks and then in response to that, perhaps we did too much. And now the pendulum has threatened to maybe swing too far back the other way.

And we're grappling with that as elected officials and you all are grappling with that as people in the bureaucracy, and I'm interested to hear from you all what you have already done, what you intend to do to build on that.

Dr. Goldman, I am not going to ask you to comment on this now, but I and 41 other House Members sent Ms. Browner on December 20th a letter about a rule, National Emission Standard for Hazardous Air Pollutions. And I assume it would have been referred to your office. And I'd like to give this to you today before you leave. We haven't heard back from you on it, and in is certain urgency about it.

I just want to raise it today and say no more about it, but ask that you please follow up on it as quickly as you could.

Ms. GOLDMAN. It would not have come to my office, but I will follow up on it very promptly.

Mr. GEREN. Thank you.

Yield back my time, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Geren.

Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman.

And again I appreciate your fairness as well as open-mindedness of this committee in terms of coming out with something that's going to achieve the purpose to which we all agree. And I thank

the panelists for being so candid in their response and their desire to work with the committee.

A question or so. Title III would appear to apply very broadly to a variety of health, safety, environmental and resource regulations. However, the terms of the bill language on the risk assessment process seem to focus almost exclusively on human exposure to chemical hazards.

So my question for the panel is: Is the proposed risk assessment procedure really relevant to the assessment of regulation on, for example, automobile safety, or the protection of wetlands or wildlife? Would you like to comment on that?

Mr. GIBBONS. We are just not sure. Let me give you an example. Within the last 48 hours, the Patent Office has described—has published for public comment a change in their regulations which would forgo any evidence of clinical trials for a biotechnology patent, which has been a sore point with the industry, we're trying to fix this thing.

As far as we can tell, that would come under this kind of legislation and would require a great deal of time and money that, if we went ahead with it now, would not. So we're just not sure how far this would apply, how comprehensive it would be.

And as you pointed out, Congresswoman, that some of the prescribed conditions really focus on cancer risks to human health. And yet the rules apply, perhaps wisely, much more broadly to the regulatory process. So we have a little time to work this out, I think we can, but it's hard to do it over a weekend.

Mrs. MORELLA. Would you all agree?

Ms. GOLDMAN. I would agree, and I think if you look on page 38 of the bill, the principles, "when assessing human health risks, a risk assessment shall consider and discuss," and then there's a long list of things. And there is no mention of when reasonable or when relevant.

Even for a human health risk assessment, say one in real life that we're trying to do today, we need to respond to the problem of cryptosporidiosis, a bacterial problem in drinking water, that's specific provisions would not apply to doing an assessment of health risks from cryptosporidia.

It may apply today to what we do for cancer assessment, but again, in the future, we may do cancer assessments quite differently. Hopefully the science will evolve, and this wouldn't even give us the flexibility to change along with that science.

Mr. COLLINS. I might also add to that, one of our programs is the Food Stamp Program. We spend \$30 billion a year on that. The thresholds that are in Title III apply to a risk characterization that's made public, then there's one set of requirements. A risk assessment that's related to a regulation that has a \$25 million impact or more, then there's another set. And then of course there's the peer review that applies to 100 million and above.

For a program that we're spending \$30 billion a year on, it doesn't take much of a change to trigger an impact. Now, admittedly an awful lot of the regulations we put out under the Food Stamp Program have to do with management of the program. But there are formula-driven changes that have a health effect.

An example is, every year we update the benefit level based on the cost of the Thrifty Food Plan, which is the basic amount of food that we feel is a minimally adequate diet for the recipients. As we change that benefit level, that changes their purchasing power ability over food. It has a health effect, a nutritional effect.

Is that kind of a formula-driven change going to be subject to all of the three thresholds that I mentioned in this title? I mean, that's a concern that we have, the broadness of the scope and the way that it applies. That's just one example on formula driven changes.

Mr. SCHULTZ. Just to add one other aspect, sometimes Congress does a risk assessment or a cost-benefit analysis, and it decides that the Food and Drug Administration or some other agency ought to implement a program. An example is the Nutritional Labeling Act where Congress decided that we ought to have nutrition labels on food. As we read this bill, it would give an agency the ability to override that congressional decision, and to basically make a different cost-benefit analysis. And I just raise that as to whether that's really something Congress would want to do.

Mrs. MORELLA. Do I have time for a question along the same kind of lines?

The CHAIRMAN. Your time has expired.

Mrs. MORELLA. It has expired. I wouldn't want to see that nutritional labeling removed, incidentally.

The CHAIRMAN. Mr. Baker.

Mr. BAKER. Thank you, Mr. Chairman, and thank you for this testimony and hearing today. It's a subject that is well needed for review.

I would like to thank the former chairman for his chart. I would suggest from the eyes of the American public that the time line and the chart of getting through the regulatory morass would not fit on that wall. The reason we're having this hearing is because we have all heard from our constituents the horror stories of what happens to them in the regulatory process. And the reason we need judicial review is not because we love lawyers, it's because that is the victim's only recourse once he gets trapped in the web.

Let me take you to page 33 that you have in front of you on the bill. The purpose of the bill, the public and private resources available to address health, safety, and environmental concerns are not unlimited. Those resources need to be allocated to address the greatest needs in the most cost-effective manner. That's what we're after.

Let me give you a couple examples. The Toxic Cleanup Act, we want to clean up all of the toxic waste sites, at which we've only labeled about a billion, including every gas station in America. Corporations, businesses, farmers, everyone else in the real world have found it more cost-effective to march to court, rather than clean up the sites. So trillions of dollars worth of legal costs later, we're in the cleaning up the sites. Doesn't anyone out there in bureaucratic land think that's a problem that needs to be addressed?

I've used this example before, but Dow Chemical 15 years ago tried to build a chemical plant in California in the bay area. After two years and \$10 million worth of legal fees, two of the 40 permits had been obtained. They went up to a green country known as

Canada, and within six months from arriving had built the plant and received all the permits.

Now unless in these 15 years the people of western Canada are dying from toxicity, something is wrong with our regulations. Wetlands, if the Corps of Engineers lands on your project, God help you. They will find a weed or a plant or something that indicates that your driveway has been wet more than 19 days last year. The relief, there is none.

If the local governments, county and city, agree with the builder that the project is necessary for their community, they can do nothing about the EPA and the Corps of Engineers as they squash the project without any relief. They cannot get an answer out of the Corps, and they cannot build.

We need change. And I'd hate to let FDA off the hook with the statement that they're getting better, because in Florida, the doctor just reminded me there was a project to build a machine that enhances the photography in a mammogram. So it never got near the patient, it couldn't have been toxic, it couldn't have harmed anyone.

What it did was enhance the mammogram to make it more easily read and more easily definable as to how to treat possible cancer. It took EPA—I am sorry, FDA, two years to approve them reading these mammograms. This is outrageous. And the public is screaming. And so we come to you with an idea, and we get a steady diet of this. Well, of course it's impossible.

So meanwhile, the farmers out there, who are being driven out of business, and the builders who are already out of business, are subject to this room full of well-fed and well-paid bureaucrats without relief. And the answer we're getting is this, "Oh, it can't possibly be done".

I share Mr. Ehlers' frustration. There was an election November 8th. Even in the most liberal Democratic Congress of 1994, basically this bill was voted out of this committee, despite the author of this chart's objections. So change is coming, and I urge you to get upon the train and help us make this world safer, but also available for human beings and human progress.

Mr. GIBBONS. May I respond to that, Mr. Chairman, just very briefly?

I don't think we have an argument. When I opened my statement this morning, I said I thought the findings were right on target, let's stipulate them. The diagnosis is correct, we are concerned and we are moving. There's a rate at which you can move that you also begin to break things. That is the only argument, not the diagnosis, but the treatment.

Mr. BAKER. Let me respond to that very quickly.

If you look on page 33 here, you will see the effective date, ending after December 31st, 1994. This is basically the same law that came out of this committee a year ago. So we're not springing something on you out of the Contract With America. We warned you.

The CHAIRMAN. The time of the gentleman has expired.

Mr. BROWN. Mr. Chairman, may I respond, since the gentleman mentioned my name by implication anyway?

The CHAIRMAN. Briefly.

Mr. BROWN. This bill that's before us is by no means the bill that came out of this committee and, as the gentleman correctly points out, the bill that came out of this committee is not a bill I particularly liked. I am committed to the improvement of the process, including through this legislation, if we can, but I don't think we should use the comparison of last year's bill with this year's bill. There are many, many serious differences.

The CHAIRMAN. I thank the gentleman. It is roughly similar to what passed on the House Floor, though, in the environmental technologies bill.

The gentlelady from California, Ms. Seastrand.

Ms. SEASTRAND. Thank you for coming here today. I think I would echo the sentiments of my colleagues, Mr. Rohrabacher, Mr. Graham and Mr. Baker. It is a pleasure to sit here today, because when I do go home on the weekends, I face constituents that say, "Is anyone listening in Washington, D.C.?"

The district I serve has many small businesses. Agriculture is very large in the area, tourism, commercial space. And what we see are people, constituents, that want a safe world. And they want products that they can sell and the consumers will be happy. They want products they can sell to the markets and have people serve on their tables that will be safe for consumption.

But I think what they're telling us, and I think the message we're trying to give, if anyone's listening, is that we have paper, we have time lines that are inappropriate, and the costs of many of these regulations that cost each and every one of us as taxpayers dollars.

Now, I've read that in the first two years alone of the Clinton administration, 126,580 pages of Federal regulations have been added on the American people, more than any other President since the last two years of the Carter administration, and I understand at the present rate, we're going to exceed the Carter administration's four-year record. Now that's a lot of regulations. And along with those regulations come the costs that I had stated are put on the taxpayer.

My question to all of you is: Are you satisfied that each and every one of these regulations was necessary, or would it have been more responsible to take a harder, perhaps objective look, at some of these regulations before they were imposed on businesses and citizens, and those that are going to be imposed in the next two years?

And this is what we're trying to tell you, is that it's wonderful to sit here, you're sitting there, putting out the pages and the regulations, and yet I go home and I have to face those constituents that are saying, how do I do this, how do I keep my doors open, create some jobs here for people to survive on the central coast of California, and I have to put up with all of this.

So that's my question.

Ms. GOLDMAN. I have a couple of things that I want to say in response to that. First, that I think that we all, again, agree with that formulation of the problem, that there have been too many burdens created and especially for some of our citizens, small business people, some of our local governments, where the regulations really have accumulated in a way over the years that has not been

reasonable. And that it is a time to take a look at that and to change that.

I think that the Vice President is leading a process to do that, that the EPA and the other Federal agencies are very involved with, and particularly to look for ways that we can address this problem for small business and local communities.

Now, one thing I do want to take exception to, however, if you will allow me, is the comment about the pages in the Federal Register because it is commonly misunderstood what a regulation is. And although some regulations create burdens and some regulations create requirements, others create permission for people to do things that they need to do.

When I register a new pesticide, I publish something in the Federal Register. Each time I allow a new use for a pesticide on a crop, a pesticide that perhaps the farmers in your district need to use, I must publish also a tolerance so that that pesticide can be used on the food and so that it's—we can be certain that the level of the pesticide for the consumers, the level on the dinner table, is an appropriate level. That is a regulation, but it is a regulation that allows people to do something that I think we want to allow them to do, which is to develop new pesticides, to innovate in that area, and to be able to use those for their crops.

I think that in closing, I think we all want to find more common sense ways to do our work, more cost-effective ways to do our work. But just counting pages in the Federal Register, I understand the anger, but the constructive way to do this, unfortunately, is we have to tease this apart and find the regulations that need to be changed, go back over the years, the pileup of regulations that need to be changed, and target our efforts toward those areas. And particularly towards those people who perhaps have unjustly received more than their fair burden.

Mr. SCHULTZ. Can I add something? We, as you know, under the Clinton Executive Order—but it's really very similar to the Executive Order that President Reagan issued—do a cost-benefit analysis for major regulations. So in that sense, we're, you know, very consistent with what this bill requires.

We—I mean, the things that we, I think, keep saying here, is that there are many things the government does that it's doing too slowly right now and it needs to do more quickly. The example of a medical device that took two years to be approved—that's too long, we need to do that more quickly. And there are only two ways we can do it more quickly. We can eliminate requirements that may have an impact on safety, or we can figure out a way to either use our resources better or get more resources.

But let's ask the question, when we evaluate this bill, is that going to have—is it going to have us do our job better, is it going to have us approve those products more quickly, or is it going to slow us down? And we're concerned that in many of these cases, people are going to be less happy with the job the government is doing if this were enacted as it's written.

The CHAIRMAN. The time of the gentlelady has expired.

There is a vote on. Mr. Doggett would be next up, but I think what we will do is recess the committee and go vote and then come back.

The committee stands in recess.

[Recess.]

The CHAIRMAN. I would ask the committee resume its deliberations.

Mr. Goldin is waiting to see me here, and I am going to ask Mr. Weldon to take the Chair briefly so that I have a chance to meet with the administrator of NASA for just a couple minutes.

Mr. Doggett would be next up. Mr. Weldon is prepared to recognize him, and then Mr. Weldon is next on the chart, so I'm going to ask him to go ahead and ask his questions in his capacity as the Chair, and then we will be prepared to move to other Members.

Mr. WELDON OF PENNSYLVANIA. [Presiding.] The gentleman from Texas is recognized for five minutes.

Mr. DOGGETT. Thank you very much, Mr. Chair.

I want to commend both the statements that have been made, but more importantly, the work that each of you are doing to protect the public health of the American people, and to certainly associate myself with statements, the bottom line of which I think is that we want to pursue constructive change for good science, but not necessarily good politics.

If we have good science, then that ought to be good public policy. And in that regard, in looking at this bill as it's currently written, is there any doubt in your mind that as currently written, it represents a serious threat to the health and safety of millions of American citizens?

Mr. SCHULTZ. There is no doubt in our mind that this bill would seriously impair our ability to do our job of protecting American citizens from the products we're responsible for regulating.

Mr. COLLINS. From the point of view of the Department of Agriculture, I would agree. It would concern us greatly. I would also add, it would also—it concerns us about the detrimental effect on agricultural business, which we've talked a lot in this hearing today about how regulation is hurting business.

An awful lot of what we do at the Department of Agriculture relates to the promotion of exports by assuring our foreign buyers that they're safe, that they're wholesome. Same is true on the import side, assuring agricultural processors, food manufacturers, that the imports that they bring in are safe and wholesome. To the extent that we're limited in implementing those kinds or impeded in implementing those kinds of activities, and all those involve risk characterizations, we reduce agricultural business and potentially agricultural exports.

Ms. GOLDMAN. There is no doubt in my mind that this bill would have a negative impact on protecting the public's health. Actions we've taken in the past, taking the lead out of gasoline, the ban of DDT, many other very important actions, would not have been able to have been accomplished or would have been delayed had we had H.R. 9 in the past.

Mr. GIBBONS. I would only add that I think the distance through which this bill can interact means, for example, things that go beyond the traditional environmental and health issues. I know, for instance, I just learned that the general counsel of NASA has raised serious concerns about the implications of this bill on the ability to move ahead with commercial space launches, for what-

ever reasons, I think NASA would have to describe. But it's that reach of the bill, and the uncertain reach that really gives us great pause.

Mr. DOGGETT. And as far as this rulemaking maze that has been so adequately identified by Mr. Brown's chart, do you have any estimate of how many millions of dollars the taxpayers will have to pay if we add that layer of bureaucracy on top of the process we have already?

Ms. GOLDMAN. EPA has estimated, and this is a rough estimate at this time, that we would have to hire 900 new people just to carry out the analytic and legal requirements under this act.

Mr. COLLINS. We do not have such an estimate at this point.

Mr. SCHULTZ. FDA does not have an estimate, but we believe it would be significant.

Mr. DOGGETT. And this is in reference to cost benefit: Most of the emphasis has been on the cost side. I'm interested on how you go about measuring the benefits side for example of a young woman not having her face scared from a defective cosmetic; of a future generation of children being able to observe an old growth forest; even the difficulty of evaluating a human life saved because we had air pollution reduced.

How do you go about doing the benefit side of these regulations under this bill? And to what extent would you be subject to being second guessed, no matter how good the science you employed to do that, by not only judicial review after you have completed the process, but perhaps judicial review when you are right in the middle of the process?

Ms. GOLDMAN. Well, today we must assess both the costs and the benefits for major regulatory actions under the Executive Order. And how we do that, to be honest, we do it the best we can. And it often is very difficult to quantify what these benefits really are.

What is a child's IQ worth? What is it worth to avoid having a child with a birth defect? What is a case of cancer worth? And we do our best, but oftentimes we are not able to quantify some of these benefits.

I think that it is also important to see that how in this bill there are opportunities for people to come in to second guess these, even before we make a decision. And even more disturbing to us, a requirement that we will include, in peer review, people who may have a financial interest in the outcome of our decision.

Mr. WELDON OF PENNSYLVANIA. [Presiding.] The gentleman's time has expired.

I'm next on the list, so I yield myself five minutes and begin by thanking our witnesses for coming in. Let me state at the outset that I'm a Republican who over the past eight years in Congress has supported much of the legislation that has passed in the Congress dealing with worker safety and environmental protection, and I'll continue to be involved in that regard in this Congress.

And I would be remiss if I didn't say I don't have some concerns about the impact here. But I have to tell you why we are here today and give you some examples that are extremely frustrating to me.

The wetlands problem was mentioned earlier. It is impossible for the business community and ordinary citizens and environmental groups to deal with Federal and State agencies that have four different definitions of what a wetlands is. There is no excuse for that.

The Environmental Protection Agency, the Army Corps of Engineers, Fish and Wildlife, and State wildlife, in the case of the State DER, all have different definitions of wetlands. It is detracting from those of you who want to protect legitimate wetlands. The agencies have got to get their act together.

You may have problems with this bill, and whether this bill becomes law is not going to be the key issue because the concerns are still going to be there even from those of us like myself who want to support wetlands of this country.

Another example, before I came to Congress we passed CERA Title III. The regulations that were imposed in CERA Title III on local community emergency response groups are outrageous. I used to be a volunteer fire chief before I came to Congress and worked all of those issues for the Congress and chaired a caucus dealing with those issues.

We imposed regulations for local volunteer fire companies, and there are 32,000 of them in America in every State and district, to be properly trained and especially protected with equipment when they go to a HAZMAT incident. The problem was that we mandated this in the regulations, but because there was no money put out there, 95 percent of the 32,000 fire departments in America could not and have not met the requirement that we imposed on them.

What good was the regulation? All it did was cause fewer people to volunteer. And those that are still volunteers don't care about what regulation you have imposed, they are still going to protect their towns because they can't afford to buy the equipment and can't go to the training classes that you mandated on them with no consideration for the impact locally. And then we have President Clinton talking about getting people to be involved in the community.

Those kinds of regulations have the exact opposite effect and hurt our towns and cities. What it further does is causes those fire chiefs and local emergency responders to be subject to liability actions in the courts because they didn't take the proper steps that were mandated by the Federal Government.

That has got to stop. It is outrageous. And while we may be trying to protect these people, we have the exact opposite effect and actually cause fewer and fewer people to want to volunteer.

And the third thing is the clean air bill, which I supported, has no flexibility. So here we have the EPA coming in and saying centralized emissions testing. Companies go out and spend tons of money and now, because of political pressure, EPA is saying we are not going to enforce those standards. That is a terrible signal to be sending. And how can States be expected to attain the desired results, to meet the attainment levels in terms of pollutants in the area?

And finally let me give you an example dealing with I think a problem that exists across the board, and that is the current system, in my opinion, breeds abuse. In particular, there have been

incidences where regulatory agencies which have little control over one element of a human risk factor try to overcompensate by regulating another over which they do have control, an example is EPA's regulation of radon and the drinking water proposed rule.

Radon may be a significant health risk, but in water, where it is one component which represents less than 1 percent of the overall risk, it really is not. What does EPA do? Because it can't regulate naturally-occurring radon, they decided that radon should be regulated in drinking water.

Ms. GOLDMAN. I would agree that we need to have more common sense and more attention to cost-effectiveness in our regulations. But I think in a couple of your examples there are things that have been done and are being done to change those.

Take the last one that you mentioned, the radon and drinking water rule. That wasn't an example of the agency trying to overcompensate in one area for another area. The truth of the matter is that we don't have an authority to regulate the contaminant in indoor air and there is no regulation of indoor radon levels. And the way we are dealing with that problem is through public education and recommending people to test and trying to make people aware if they live in areas that are high radon areas.

In the case of the drinking water contaminant level, that is something that Congress told us very precisely to do. In the last section of the Drinking Water Act a list of contaminants was given to the agency and we were given deadlines to meet in order to set levels for those contaminants.

We have come back to Congress—last year we came back to Congress and asked for more flexibility in how we set our drinking water standards. And we continue to ask for that.

H.R. 9 will not do that, though. H.R. 9 will not override that list in the Safe Drinking Water Act. The only way to do that is to look at the Safe Drinking Water Act.

Mr. GIBBONS. I have a couple of comments, Mr. Chairman. The last administration actually held up the movement toward trying to get a consistent definition of wetlands, and you are right, it is badly needed. There is an interagency task force that has undertaken that, and I understand there is now a consistent Federal executive agency-wide definition of wetlands that we will try to utilize.

Second point has to do with overprescription and lack of flexibility. We have been working with industry through our so-called environmental technologies initiative, and one of the firm bottom lines we come to is the value, the promise of performance-based standards. We would like to work hard on this and we intend to do so, but that is not a part of this legislation either.

Mr. SCHULTZ. There are two kinds of problems. One, is there a problem with the statute or are we doing something that Congress doesn't want us to do? And I think we should engage in that discussion.

Secondly, are we doing something as a matter of discretion that I don't think we ought to be doing, and that is a matter of oversight.

Thirdly, if there are particular areas, we ought to look at them one by one. Take peer review. Okay? The FDA does a lot of peer

review, as I indicated, but if there is a feeling that we ought to be doing it elsewhere, then let's talk about that specifically.

But what we are saying—we are not saying we are doing it right and we have hit the right balance. What we are saying, we don't think it is going to be productive just to tell us to do it everywhere because that is overkill. That is really our problem with the bill.

Mr. WELDON OF PENNSYLVANIA. My time has expired.

The gentleman from Massachusetts, Mr. Olver, is recognized.

Mr. OLVER. Would this bill change the way we define wetlands? There is nothing in this bill that would have affected at least that example, though it may be a matter of great concern over all regulatory issues.

Mr. GIBBONS. No.

Mr. OLVER. I was obviously very amused or bemused by the chart that was put over there. I wonder if we were to compare the chart that is there versus what is the present circumstances with a similar chart for the present circumstances, and then probably—I'm a scientist in an earlier life—and then actually see if one could get the two sides of the aisles to prepare their own charts, I think that probably in theory one ought to be able to come to an agreement of what that chart is, both now and in the future, and what the time lines would be on it.

I must say I'm concerned in this process that the risk assessment approach that is coming out of this legislation would come close to what a great many of my constituents have always worried about how the environmental impact statement approach evolved over a period of time for a different set of purposes where probably the many projects ended up being strangled by the dollars that were used in spending to the consultants and the lawyers along the way, and also ended up being drowned in the paper that ended up in the creation, and the time and the paper and so forth that went into the environmental impact statements.

But I wanted to raise a question to Dr. Goldman on EPA. In the time that I have been able to be here, it was only in the last few minutes when the question of lead in gasoline was mentioned. And at our testimony last Tuesday, the first hearing on this item, the removal of lead in gasoline was given both by the testifiers and agreed to by the Chairman of the committee—I think he agreed to it—as a prime example of really sound cost benefit analysis.

And I guess I would like to ask whether this bill would make your job in reaching that sound analysis, cost benefit analysis, make it easier, or make it quicker, or would it be slower? Would we still be tied up in court or not?

And then given the present circumstance and the proposals under that bill, while I doubt if you can do it off the top of your head now, whether you could go back and analyze for us what actions the agency would have taken under Title III here in the ban on lead in gasoline, how swiftly that would be accomplished under the new legislation in order that we could assess whether it would improve the circumstances or not.

And maybe you could give us an idea whether there are advantages in the way this bill is written to doing what you needed to do in which most of us agree was really sound cost benefit analysis

and what would be the areas of disadvantage in it. That is a rather long question, but maybe you can—

Ms. GOLDMAN. Okay. Let me attempt that.

I think that it is important to remember that although today in 1995 the decision to phase lead out from gasoline appears to have been the correct solution, the right thing to have done, that at the time when it was first proposed, that it was a very controversial action and it was a very difficult decision. And what made it very difficult was the following: one, there was a lot of money invested in the industry for producing and using tetraethyl lead.

Two, there was a lot of controversy about whether unleaded gasoline could be used in our vehicles, whether our vehicles could withstand—the gasoline that we all use today at the time, there were some legitimate concerns. And thirdly, there were many—as there are still today—controversies about precisely how you assess the risks from lead.

And as I'm sure Mr. Olver is aware and many of the committee Members are aware, the final decision of removing lead from gasoline was totally based on a cost benefit approach that didn't even take into account the health benefits, the benefits for our children because they were so difficult to quantify. Totally needed to rely upon the other economic considerations.

What we would be concerned about today with H.R. 9 is that there would be, as you can see on the chart, far more opportunities for litigation as though kinds of analyses are being created as we look carefully at both the human health side and the economic side. And that because there was such a significant investment in that technology, the technology of using leaded gasoline in our automobiles, there were people who would have done almost anything to have stopped that phaseout. It was very difficult getting there.

This would make it far more difficult and we probably, quite possibly, would still have a number of litigations today or the benefits to our children of having taken the lead out of gasoline and the dramatic lowering of blood lead would have been delayed by several years which would have been a terrible mistake.

I think what is good in here is where there are general principles that are espoused that we believe in and that we think we should be required to adhere to. And I think all the agencies, whether on this panel or not, would agree that as the Executive Order tells us to do, that we should be looking carefully at the benefits of our regulation. We should be looking carefully at the costs. That when appropriate, we should be bringing scientists in from outside of the government to provide information and to peer review.

These should be put forward though as performance standards and we have to do this with a rule of reason. We have to do this with some consideration for relevancy in mind. And what is bothersome is when you see things like language that says, we shall to the extent that—to the extent feasible include all scientific studies that might be relevant.

Somebody could come forward and say there was an article in the 1920 Journal of Tibetan Medicine that you didn't use or something like that, and it would have been possible to find that and that could create a grounds for a court challenge. But yet scientif-

ically perhaps that study wasn't relevant, would not have been reasonable to have included it.

And there is just time after time in here where there would have been opportunities to use language like that to make it clear that this is to be a reasonable exercise when that is not done.

Mr. OLVER. Mr. Chairman, I would like to put my question in paper to the EPA and allow them to answer if that could be added to the record, if we get an answer in time.

The CHAIRMAN. Without objection, the gentleman may submit questions in writing.

The Chair wishes to begin here by correcting a couple things which I think I would disagree with the assertions that have been made by the panel in a couple of instances about H.R. 9, Title III.

First of all, Mr. Collins indicated that there was no definition of emergency in the bill. It is very clear that the head of the agency has the ability to define emergency. And so therefore in some of the instances that you cited if in fact it represented a true emergency, there is no doubt that the head of the agency could take care of that particular situation.

There is no explicit judicial review in the bill. Whatever judicial review that would result would result as a part of present law. And so therefore are not expanding the judicial review process. I assume what is being said is that we are expanding some opportunities for some people to get into the judicial review process, but it is interesting, the people who you are complaining about having judicial review are the people that you have been tying up with massive burdens of regulation, and so now when they get their chance to enter the process, now scream bloody murder about the judicial review that you had working for you. Now, it seems to me that we have got a bit of a problem there.

And then I also, Ms. Goldman, you have referred several times to page 38 and said—and questioned the flexibility on page 38 on a number of items. I would remind you that down in the language it says “as appropriate”. It does give a tremendous amount of flexibility by adding the words “as appropriate” to the line of things that the agency would be required to do.

Let me also then,—I have a question I'm going to come back, but for right now I want to deal with the chart for a minute since each of you has decided the chart represents reality here, and have been pointing to it and referring to it.

My crack staff has spent a little bit of time looking at the chart. Let me indicate the boxes on this chart that apply to Title III of rule—of H.R. 9. This box, this one, this one, this one, this one, this one, this one, this one, and this one. Nine out of the fifty-six boxes have anything at all to do with Title III.

And so therefore this chart does in fact have a few problems. We have also looked at this little corner up here. Five of the six boxes in this little corner up here are present law. So indeed, there is a bit of a problem in that case.

And then we got down here and we find a box here talking about OMB review per Executive Order 12/2/91. Turns out that particular Executive Order is President Reagan's Executive Order of 1981 that was repealed by President Clinton in 1993 in September of

1993. And so that particular box has absolutely nothing to do with relevant laws.

Mr. GIBBONS. Mr. Chairman, do you invite a response?

The CHAIRMAN. All I'm saying is that before we suggest that somehow H.R. 9 is the problem here, I think we ought to recognize that what H.R. 9 is attempting to respond to is a massive quantity of bureaucratic regulation that has been in place for a long time that has tended to impact on business rather than bureaucracies and what does strike me is a lot of what we have heard today is that people say, oh, my goodness you can't have bureaucrats required to live under these things. We shouldn't be required to do the same things we have been requiring for business. And I'm simply suggesting that maybe we could get a lot more rationality if bureaucracies were required to live under the same laws that we have been imposing on business.

I'm happy to yield to you.

Mr. GIBBONS. As I understand the chart, it was not intended to just represent Title III, but the bill, H.R. 9.

The CHAIRMAN. But this committee is dealing with Title III.

Mr. GIBBONS. I also believe that the Executive Order that you just mentioned of President Reagan's is actually embedded in Title VII of the bill. So it is there. It is reconstituted as a consequence of the bill.

The CHAIRMAN. This committee has no jurisdiction in Title VII.

Mr. GIBBONS. I have a hard time separating myself and only looking at Title III. It is little too narrowly focused because a lot of the actions in Title III are also in Title VII. And I'm not sure that the two committees are in that close communication with each other because some of the provisions in fact are in conflict.

The CHAIRMAN. And as I pointed out earlier, there is an attempt to make certain that there are some communications going on here to try to resolve any of those kinds of problems.

But you know, this committee has a responsibility to deal with Title III to represent this and to have testimony here representing that what we are doing is creating a brand-new bureaucratic maze is, in fact, totally outside the scope of what we are doing. And I'm simply suggesting that much of what is on that chart is evidently things which are embedded in present law that only apply to the private sector.

And we need now, it seems to me, to understand that a lot of what we are hearing complaints about here are exactly what the private sector—let me give you an example. EPA, I understand, has a significant rulemaking underway for the pulp and paper industry. They are, using EPA's own estimates, the rule will cost industry over \$4 billion. The industry disputes these figures and estimates that the cost is \$9 billion.

But regardless of whether it is \$4 or \$9, the outcome is going to be that the agency now estimates the modest benefits will be a maximum of \$200 million and could be as low as \$10 million. Now, clearly to spend \$4 billion to get the benefits that at the maximum are going to be \$200 million has some problems with it.

Can you tell me what got out of whack here?

Ms. GOLDMAN. Let me start out. First I want to make it clear that our analysis of H.R. 9 is that the things that will be required

of the government will create requirements for others as well. Every time we do an assessment, every time we do another analysis, someone has to provide us with the data and the people who usually have to do the effort to provide the data is the regulated community.

And so I think that it is a mistake to say, you know, you are asking us to live under requirements that other people have now. Today the regulated community doesn't have these requirements. If enacted, H.R. 9 will impose requirements on others. And I would urge you to look at that carefully and think about the pesticide registration.

The other thing you need to think about in terms of opportunities for litigation is that there are many who may choose to sue over decisions that we might want to make. Not just the regulated community, but others. There are those who object to almost every pesticide registration decision that we make.

This provides opportunities for them as well as the regulated community. There are competitors within our industries who may sue to block a new product, an innovative new product that will compete with their product and we don't want to see that kind of mischief occurring.

As to the numbers that you gave for the pulp and paper rule, they nowhere match the numbers that I have. And I think we are going to have to get together to look at that. The numbers that I have would indicate that at least the most recent analysis that the costs and the benefits are estimated to be about the same. They are both under \$1 billion, certainly not \$2 to \$4 billion. And that in fact there are benefits to the rule that we cannot quantify.

Benefits such as removing odors from communities, making ecosystems cleaner and healthier, which we can't quantify and don't count in our analysis. So I don't understand the discrepancy between our figures, but that is something that we need to work out.

The CHAIRMAN. Well, this is the source, The Cost of Federal Regulations, Journal of Regulations Social Costs, 1992 is where I got my information.

But, I mean, you know, now you say there are things that you can't—that you can't calculate and so on. And one of the calculations is that we are going to have 33 pulp and paper mills that are concerned about closing. That would be an 18,000 direct and perhaps 86,000 indirect job loss in that industry as a result of what we are doing. That is just my own estimate, that is 1,857 workers for every box on that chart.

Ms. GOLDMAN. It is clear—

The CHAIRMAN. My guess is that there are an awful lot of those folks who probably regard a slight odor in the communities being something that should be weighed against their job.

Ms. GOLDMAN. It is clearer to me now why our numbers are different. The numbers that you citing are from a rulemaking that was being carried out in the last administration and we have been working with the industry and the other stakeholders to come up with a more common sense for practical and cost effective way to get at the problem.

We certainly do not want to follow the course that they were on when we came into office in 1992 with that industry because we were very concerned. And I can pledge with you that we are going to work with that industry to come up with some solutions that make sense.

The CHAIRMAN. Well, and I appreciate the fact that the bureaucracies are not much better under Republican administrations than they have been under any others because they are driven by a set of absolutely crazy rules and laws that Congress has passed over the years. And what we are trying to do is get back to? Sensibility that would allow some of this to happen with good sense.

And I appreciate the willingness to work with us to try to develop those kinds of areas.

Mr. GIBBONS. Mr. Chairman, I'm glad you brought that up at some point we might want to talk about statute by statute review of these regulatory things because that way you can tailor the response to this very multifaceted field in which regulation occurs.

I would love to work with you.

The CHAIRMAN. I understand, Dr. Gibbons, that one of the problems is that when we suggest that we want to do that, that is regarded as retroactivity in going back and, at that point, people become very disturbed that we are going to emasculate all of these wonderful laws that have been put in place.

And so one of the reasons that we are talking about doing things prospectively is so that we don't have the criticisms of the other vein. I have taken more time than I allocated to some other people, but I did want to correct the record here before we went on.

And I do thank the panel very much for your participation and particularly for your willingness to work with us on some of the issues that we do want to resolve. We want to make this good legislation and find out ways of making this workable and not unworkable.

Mr. GIBBONS. Mr. Chairman, thank you very much for what I think has been a very informative session for us. We appreciate your patience and enjoyed the morning.

The CHAIRMAN. Thank you. Thank you very much.

I recognize Mr. McHale to introduce his constituent and I understand Mr. Doggett also has a constituent here.

Mr. McHale.

Mr. McHALE. Mr. Chairman. I thank you. To say I have a constituent here is a significant understatement. I have a friend, whom it is my pleasure to introduce to this committee, and when I say that, it is a little bit presumptuous because the constituent who is about to testify served as a Member of this committee longer than I have.

The constituent I now introduce is former Congressman Don Ritter. Don, we welcome you today. Delighted to have you here. Let me very briefly present to the committee a very distinguished biography on behalf of Mr. Ritter. Don is the Chairman of the National Environmental Policy Institute, a nonprofit, nonlobbying, bipartisan organization. The institute's goal is to develop balanced solutions to environmental problems based on sound science, rational assessment of risk, and solid economics.

Don served seven terms in the United States House of Representatives. He was my predecessor in this office representing Pennsylvania's 15th congressional district. One of just a handful of 435 Members of the House with a technological background and the only one of two at the doctoral level. Don earned his Master's and Doctorate of Science degrees in physical metallurgy from Massachusetts Institute of Technology. And a Bachelor of Science in Metallurgical Engineering from Lehigh University.

In summary, let me indicate that Don's interest in the reinvention of EPA is not just legislative and regulatory. While in Congress, he pioneered the cause of Total Quality Management and like activity to empower employees and develop teamwork and be responsive to customers.

Don is the recipient of numerous honors. I don't want to consume time by going through them in detail, but he is a member of the American Society of Metals, the National Society of Professional Engineers, he is also a fellow of the American Institute of Chemists.

Don, I am delighted to see you here today, and welcome you. I look forward to your testimony. And I am confident that not only on a professional level, but on a personal level the Members of this committee are delighted to see you return.

Welcome.

**STATEMENTS OF DR. THOMAS A. BURKE, JOHNS HOPKINS UNIVERSITY; DR. PAUL PORTNEY, VICE PRESIDENT AND SENIOR FELLOW, RESOURCES FOR THE FUTURE; THOMAS O. MCGARITY, WILLIAM STAMPS FARISH PROFESSOR OF LAW, THE UNIVERSITY OF TEXAS; DR. TERRY F. YOSIE, SENIOR VICE PRESIDENT, E. BRUCE HARRISON COMPANY; DON RITTER, CHAIRMAN, NATIONAL ENVIRONMENTAL POLICY INSTITUTE; AND THORNE AUCHTER, INSTITUTE FOR REGULATORY POLICY**

Mr. RITTER. Thank you very much. Does that mean I get to go first, Mr. Chairman?

The CHAIRMAN. I think I am going to recognize you, Mr. Doggett, and allow to you introduce your constituent, Mr. McGarity.

Mr. DOGGETT. Thank you, Mr. Chairman. I am pleased to present Professor Tom McGarity from the University of Texas Law School, my Alma Mater, and one of many experts in Austin, Texas who we are pleased to have come up to Washington. In this case, we bring someone who has unique expertise in both science and law which is of vital importance to this committee.

Professor McGarity is degreed in both physics and law, a rare combination, though one that could prove to many to be very available in this Congress, I would think. In the mid-1970s he spent two years as an attorney advisor with the Environmental Protection Agency where he became interested in this whole problem that we are dealing with today of rulemaking and putting it on a more rational basis.

Since then he specialized in this and related fields at the UT Law School. In my previous job as a justice on the Supreme Court of Texas, I have had an opportunity to rely on his scholarly work in my own writing of judicial opinions. He is a prolific writer on

a wide range of topics very relevant to what we are doing today and one of his books, the Law of Environmental Protection, has really become the standard reference in this field. His subjects and his expertise, I know will be valuable to the committee and I appreciate your coming up today for this, Tom.

The CHAIRMAN. Thank you Mr. Doggett, and we appreciate your introduction and we will look forward to hearing from Mr. McGarity.

I think we are going to go in the following order: Mr. Burke, then—Dr. Burke, Dr. Portney, Mr. McGarity, Dr. Yosie, Mr. Ritter, and Mr. Auchter.

So Mr. Burke we ask to you lead off.

Mr. BURKE. Thank you, Mr. Chairman. I am happy to be here today to discuss the risk provisions of the proposed Job Creation and Wage Enhancement Act, Title III.

I am an Associate Professor in the School of Public Health at Johns Hopkins and, I guess, a potential peer reviewer. So I welcome the opportunity to comment on this bill. But I come to you today to offer comments really as a risk assessor and an epidemiologist, a public health practitioner, because before joining the faculty at Johns Hopkins, I served as Deputy Commissioner of Health for the State of New Jersey and before that for nine years, I was the chief scientist at the regulatory agency, the New Jersey DEP.

I established the risk assessment programs there in that State, and I used risk assessment to advise three governors of both parties. And I have had extensive experience as the recipient of unfunded mandates and the implementor of Federal policies, but also as a risk assessor.

I have had to close the Jersey beaches during the height of tourist season and run the New Jersey asbestos program with a very heavy Federal hand present always in that. So I very much support your efforts to improve the risk assessment process, particularly to develop more consistent methodologies, improve peer review, and to update the scientific basis for what we are doing here.

But I do have four areas of concern for your consideration. The first you have heard about, so I will just quickly go over it, from Jack Gibbons today, and that is the scientific basis for risk assessment. I am also concerned about the information base that we, the risk assessors, have to use when we do risk assessments.

Perhaps I am most concerned about the infrastructure for implementing the proposed approach, particularly the State infrastructure. And I am also concerned that in our effort to regulate, or obsession with regulation, we may have forgotten about good basic public health.

First of all, the scientific basis of risk assessment forces us to use a lot of assumptions. There is tremendous uncertainty. We assume about the relationship between mice and humans. We assume about dose and response threshold. It is a very uncertain process. And having lived through a lot of peer reviews, this certainly makes it a very contentious process, and obviously very contentious peer review sessions.

But if it is so uncertain, why do we use it? Most of the time that I used it it was for prevention, not prediction. It is better at identi-

ifying problems and preventing probable health issues than to predict best estimates of risk.

The information base we have to use is unfortunately very limited. Only a small fraction of the chemicals that we commonly use in this country have really been the subject of extensive evaluations and most of the chemicals that we do use we are just beginning to understand the noncancer health effects.

In addition to this, there is a tremendous gap in what we know about exposure. As much as we have spent on Superfund, we still can't give the public that has to live around the fence line of these sites an honest answer about what their exposure has been because of their living around these sites. This is true for Superfund and indoor air and it is still true for drinking water.

How many compounds are we really exposed to? At what levels? And how are our regulatory programs really reducing our exposures? The truth is we don't know. And I couldn't bring you a peanut butter sandwich, but I brought you a sample of New Jersey air. This is an air sample taken from the wonderful town of Perth Amboy, New Jersey and to point out each one of these little lines here, these mountains are chemical compounds detected by a gas chromatograph.

A risk assessment would typically look at one of those lines and try to assume what your risks are. In fact, we can't even identify most of those compounds. Our information about exposure is very frail. Strengthening risk assessment has to mean strengthening our information.

In addition to the information base, I am concerned about the infrastructure. I just completed a major study of the State capacities to implement environmental laws. For the most part, our national environmental policies depend upon the capacity of the States to implement them. The responsibilities are often very quickly delegated to the States. I know. I had to do these things. Okay?

And our national emphasis on regulation and enforcement has actually diminished our capacity to address fundamental issues of public health. Most of the money going into environmental protection goes to the regulatory and compliance side. Very little really into the risk evaluation side.

According to our estimates, about only 8 cents of every dollar that is spent on environmental protection in the States actually goes to understanding risks. Most of it goes to regulatory compliance.

Presently at the State level, because of this, there is a critical shortage of manpower, expertise, and the support that would be necessary to properly implement the risk provisions of H.R. 9.

Another infrastructure issue I am concerned about is who does risk assessment? Is it anyone who can afford risk software or are we going to have appropriate training for the risk assessors for the peer reviewers? I think the success of your efforts will depend upon the availability of competent risk assessors in both the public and private sectors and a partnership with the academic community to provide training, research, and peer review.

Finally, I would like to talk about the public. The regulatory approaches of the past 20 years have shifted the emphasis of our fundamental environmental goals away from public health. As we

have regulated substances and sources and media, unfortunately we have ignored the very people we are trying to protect.

Have these regulations actually reduced exposures or reduced disease? Have we improved the health of the public? Regulatory risk assessments with all their exponential notation provide very little information to the public on the actual reduction of risk.

Effective credible risk policies provide not only peer review and a process, but also a commitment to understand exposure to work with the people, the public involved. At some point, we need to get the information to validate these estimates and to inform the public about what their risks are.

In closing, I would like to express a concern that I realize was raised today in listening to the arguments and the debate. I am familiar with the process, as a former regulator, of what I call dueling risk assessments. I watched in amazement often as an environmental regulator as the environmental agency on the one side and the regulated community on the other side presented their risk assessments and they were at opposite ends of the pole. And I came to the conclusion that with the inherent conflicts in risk assessment, you can argue forever, that some of the things that we call science that we may disguise under the guise of good science are all about regulatory philosophy, and it has led me to wonder whether this conflict we have is more about regulatory philosophy. I think it really depends whether you are trying to prevent adverse effects or whether you are trying to justify pollution or deregulate. And I think we have to come to grips with this.

I sincerely hope that H.R. 9 with its emphasis on best estimates and peer review and identification and issues like that, will not escalate this dueling risk assessment process, but will help us cut through some of these issues and actually improve what we know about risks, not frustrate the public any further, but support our efforts to protect public health.

Thank you.

[The prepared statement of Dr. Thomas A. Burke follows:]

STATEMENT OF  
DR. THOMAS A. BURKE  
ASSOCIATE PROFESSOR OF HEALTH POLICY AND MANAGEMENT  
JOHNS HOPKINS UNIVERSITY SCHOOL OF HYGIENE AND PUBLIC HEALTH  
  
ON TITLE III OF H.R. 9  
THE "JOB CREATION AND WAGE ENHANCEMENT ACT OF 1995"  
  
BEFORE THE  
COMMITTEE ON SCIENCE  
U.S. HOUSE OF REPRESENTATIVES  
FEBRUARY 3, 1995

Mr. Chairman and Members of the Committee:

I am grateful for the opportunity to testify on the risk provisions of the proposed Job Creation and Wage Enhancement Act of 1995, Title III. I am Dr. Thomas Burke, Associate Professor of Health Policy and Management at the Johns Hopkins School of Hygiene and Public Health. I am also an elected member of the Council of the Society for Risk Analysis, a member of the National Academy of Sciences Committee on Risk Characterization, a co-founder of the Association of State and Territorial Health Risk Assessors, and I served on the Office of Technology Assessment Panel to Evaluate Risk Assessment Research in the Federal Government.

Prior to joining the faculty at Hopkins I served as Deputy Commissioner of Health for the State of New Jersey and was responsible for leading the State's environmental health programs. I also have experience as an environmental regulator, serving nine years with the New Jersey Department of Environmental Protection, six as Director of Science and Research, the agency's chief scientist. I established the risk assessment programs at both the New Jersey Departments of environmental Protection and Health, and have used risk assessment to advise three Governors, to shape enforcement actions, to set standards, and to reassure communities concerned about environmental exposures. I currently teach risk assessment at the School of Public Health, and conduct research aimed at improving the application of science to environmental health policy. I am an epidemiologist and a risk assessor, with plenty of experience in the practical realities of using risk assessment. I would like to speak to you today from the perspective of a public health practitioner.

I very much support efforts to improve the risk assessment process, particularly to develop more consistent methodologies, improve opportunities for peer review, and to update the scientific basis for risk estimates. However, I have a number of concerns about establishing an overdependence upon risk assessment and cost-benefit analysis as the primary vehicles for shaping our national approach to managing and preventing public health and environmental risks.

I would like to address four areas for your consideration:

- The scientific basis for risk assessment
- The information base for risk assessment
- The infrastructure for implementing the proposed approach
- Improving the public health basis for regulatory decisions.

### **The Scientific Basis for Risk Assessment**

Risk assessment as now practiced was developed to provide a method to organize experimental and observational data and relate it to the human population. It is a valuable but crude tool, laden with assumptions and value judgements through every step of the process. For example, we make assumptions about the similarities between mice and humans, about high exposures in worker populations and low exposures in the general population, and about the relationships between dose and response. We also make assumptions about thresholds or no effect levels. Finally, we make assumptions, based largely upon unvalidated models, about the levels of exposure in the population. Because of this, risk estimates are fraught with uncertainty, often spanning orders of magnitude. Believe me, this uncertainty makes for a contentious decision process and very interesting peer review sessions!

If the process is so uncertain why use it? The strength of risk assessment is in prevention not prediction. It is an excellent tool for developing a sense of perspective on risks - a range of potential risks which can be a valuable guide for decision making and prevention efforts. It is not, however, capable of providing accurate point estimates or "best estimates" of actual risks to the public. I urge that the sponsors reconsider the requirement for agencies to develop "best estimates" of risk.

### **The Information Base for Risk Assessment**

A risk assessment can only be as good as the information it is based upon. Unfortunately, the information base for risk assessment is very limited. Only a small fraction of the chemicals in common use have had extensive toxicological evaluation. The numbers are even smaller for those hazards which have been the subject of human epidemiological studies. Even for the most studied of chemicals we are just beginning to evaluate the range of potential non-cancer health endpoints which may include effects on our immune systems, nervous systems, or reproductive health.

Our information base is equally weak when it comes to understanding our actual levels of exposure to chemicals. I participated in an extensive evaluation of the national data bases on exposure which found a "striking absence of data on actual human exposures". (Sexton et al., 1992) From Superfund sites to the food supply, indoor air to drinking water, we know very little about the exposures of the public. How many compounds are we really exposed to in our daily lives? At what levels? Have our regulatory programs really reduced our exposures? Truth is, we don't know! This knowledge is fundamental to any accurate assessment of risks. It should also be fundamental to our national efforts to prevent disease from environmental exposures. Improving the information base for risk assessment is essential to developing more cost effective approaches to managing risks. This should be a part of H.R. 9.

### **The Infrastructure for Implementing the Proposed Approach**

The success of our national risk policies, particularly environmental policies, depends upon the capacity of the states to implement them. For the most part, the responsibility for implementing or national laws has been delegated to the states. This includes responsibilities for permitting, enforcement, and remediation decisions which are guided by risk assessments. Therefore, the major proportion of regulatory risk assessments are actually done at the state level. The requirements of H.R. 9 will impose a tremendous burden, an

unfunded mandate, on the states.

I have just completed a major study of state environmental programs throughout the nation. (Burke et al., 1995) A glaring weakness which was revealed in this study is the lack of support for state agencies to conduct the necessary public health surveillance to evaluate community exposures, identify community health impacts, and understand risks to the public from the environment. Over the past twenty years our national laws have led to a decline in the role of state health agencies in environmental protection, and a proliferation of state level mini-EPAs. Our national emphasis on regulation and enforcement has diminished our capacity to address fundamental questions from the public about risks to their health. Presently, at the state level there is a critical shortage of the manpower, expertise, and support which would be necessary to properly implement the risk provisions of H.R. 9.

Another infrastructure issue which is critical to improving risk assessment is the training of the workforce and the development of a strong academic base for risk research and education. Who does risk assessment? What is the appropriate training for risk assessors? What are the core competencies necessary for risk practitioners? Right now there is a tremendous variation in the competency of those conducting risk assessments, and it shows in the quality of their work. The success of Title III of H.R. 9 will depend upon the availability of competent risk assessors in both the public and private sectors, and a partnership with the academic community to provide training, research, and peer review.

### **Improving the Public Health Basis for Regulatory Decisions**

The regulatory approaches of the past twenty years have shifted the emphasis away from our fundamental public health goals. We have regulated specific substances, specific pollution sources, or specific environmental media. Unfortunately we have often ignored the very people we have been trying to protect. Have these regulations actually reduced exposures? Have we reduced disease? Have we improved the health of the public?

Regulatory risk assessments, with their inherent uncertainty, rarely provide satisfactory answers to these basic questions. Answering these basic public health questions requires a basic public health approach. Effective, credible risk policies will require not only an improvement of the risk assessment process, but also a concurrent commitment to the basic public health principles of prevention, exposure evaluation, and population health surveillance. Better integration of public health principles can strengthen the risk assessment process and improve our ability to communicate risks and respond to public concerns about their health.

H.R. 9 offers an opportunity to refine our regulatory efforts and focus our resources on those hazards which pose the greatest risks to our population. The development of a better balance between the costs and benefits of regulation will require tangible measures of effectiveness. This should include not only improvements in the risk assessment process, but also fundamental improvements in the public health basis for decisions.

In closing, I would like to express one final concern about a seemingly endless process which I call "duelling risk assessments". As a regulator, I often watched in amazement as government and industry experts argued over the fine points of risk assessments. The fact is that, with the inherent uncertainty in the process, you can probably argue over "best estimates" forever. At some point, difficult risk decisions must be made - risk assessments are not going to make those decisions for us. I sincerely hope that H.R. 9 with its emphasis on best estimates, peer review, and certification of cost justification, will not get us into an endless loop of arguments which will further frustrate the public and undermine our efforts to protect public health.

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The CHAIRMAN. Thank you, Mr. Burke.  
Dr. Portney.

Mr. PORTNEY. Mr. Chairman and Mr. Former Chairman, distinguished Members. I also wish that Representative Wolf were on this panel so that I might have gotten an introduction as nice as two of my copanelists here. I have done the Nation a favor by having creating a new wetland, as I spilled my water glass here. I hope I am not subject to Section 404 permitting.

I am delighted to have the opportunity to be here, and I want to say that I envy you and your fellow Members of Congress the opportunity that you have in front of you. And that is the opportunity to reform a Federal regulatory system that for a long, long time has provided significant benefits to the citizens of the United States, but at the same time has generated very, very significant costs. And the challenge you have before you is to reshape the system in such a way that we continue to reap the benefits, but shave the costs dramatically and make this regulatory system efficient and effective.

I am going to concentrate in my remarks today primarily on respects of Title III, and I will also mention something on Title VII of which I am somewhat critical. Before I do that, I want to make three brief prefatory remarks.

First of all, I want to say that in my opinion we have carved out consistently a too small role for economic considerations in Federal regulation to this point. Specifically, in my opinion, provisions in our Federal regulatory laws that prohibit regulatory administrators, whether at EPA or OSHA or the Food and Drug Administration, et cetera, that prohibit them from even taking costs into account as one factor in setting important regulatory goals, in my judgment, are a big mistake.

It doesn't make sense to say you cannot even look at costs in establishing the goals of Federal regulatory programs. And yet the Clean Air Act, the Safe Drinking Water Act, the Occupational Safety Act and other Federal regulatory statutes contain such prohibitions.

Second, because several weeks ago I wrote an op-ed piece that was critical of the Contract With America and particularly the Job Creation and Wage Enhancement Act, I want to say that the changes that have been made, especially in Title III since that time, have been most constructive and if we continue to make changes in Title III, I think we are going to have a provision dealing with risk assessment and cost benefit analysis that can be quite workable and go toward the goals that I sketched out earlier.

Finally I want to say that no matter how constructively H.R. 9 and Title III are improved, I don't view them as a substitute for statute-by-statute changes in our regulatory laws in which we look at the provisions dealing with the role of risk assessment and benefit cost analysis. This can go a long way toward improving the system, particularly if we tinker with those parts of H.R. 9 right now that, in my opinion, still need work, but we need to address the individual statutes one at a time.

Having said that, let me speak briefly about those provisions of Title III, and I will mention one provision in Title VII that gives me some concern.

I began by talking about Section 3201(a)(5)(C). That is the requirement in Title III that says that a regulator must provide a certification, and I quote, "that the benefits of a regulatory action justify the costs." And my question is, I am not sure just what this means. I am an avid proponent of benefit cost analysis. Make no mistake about that. But as avid as I am, were I to put myself in the role of being a Federal regulator, I am not sure what it would mean if I had to certify that benefits were greater than costs.

I realize this is a definitional matter and if the Members of this committee have in mind something like the statement, "in my judgment, the benefits of taking this action justify the costs and here are the data upon which this judgment is based", then I don't have any trouble with that. Because ultimately in my belief there is no substitute for having people running the regulatory agencies who have good judgment.

If the word certification is construed to mean some kind of proof, then I am afraid that this provision is unworkable and my concern about that is that by overloading too much on benefit cost analysis and expecting it to deliver something that I think it is inherently incapable of delivering, I am afraid we are going to lose not only the baby, but also the bassinet with the bath water here.

By loading up too much on quantitative risk assessment and benefit cost analysis, I don't want to trigger a backlash against regulatory reform that deprives us of the opportunity of making much needed changes in our Federal regulatory statutes.

I have some concerns also about Section 3201(C)(1). Those are the provisions that require that, in doing a benefit cost analysis, indirect costs have to be taken into account. There are literally hundreds of indirect costs or effects that can accompany a regulation. I don't want to see regulatory agencies so bogged down in having to consider every possible indirect cost or effect that they are never able to get a regulation out.

Concerning that provision, I would also say that I hope we are as interested in indirect benefits in reforming Federal regulation as we are in indirect costs. I am assuming from the most enlightened preamble to Title III that that is in fact the case, but I would note that.

I want to conclude by saying one thing about Section 7005. This takes us outside of Title III, but it does deal with the requirements to do a regulatory impact analysis in support of a rulemaking. And this goes to the heart of benefit cost analysis as that is written now.

As that section is written now, it says that no agency may promulgate a final regulation unless the Director of the Office of Management and Budget has approved in writing the regulatory impact analysis prepared by the regulatory agency.

And I want everybody to be clear in thinking about that provision that what it means is that the Director of the Office of Management and Budget will also become the Director of Federal Regulation, because there are enough uncertainties in benefit cost analysis and quantitative risk assessment that it will always be possible for any Director of OMB, no matter who he or she may be, to find some kind of fault with the regulatory impact analysis. And we can't move ahead with any rulemaking until there has been

written approval of the analysis. We will have made a very significant change in the way Federal regulation is carried out.

You all have been very patient with all the panelists today and I want to make sure I don't infringe on my fellow panelists' time.

Thank you for giving me the opportunity of being here.

[The prepared statement of Dr. Paul Portney follows:]

**H.R. 9: THE JOB CREATION AND WAGE ENHANCEMENT  
ACT OF 1995**

**Statement of Dr. Paul R. Portney, Vice President  
Resources for the Future**

**To**

**Committee on Science  
United States House of Representatives  
Washington, DC**

**Friday, February 3, 1995**

## Statement of Paul R. Portney

Mr. Chairman, former Mr. Chairman, and distinguished Members. Thank you very much for inviting me to be here today. I'm very pleased to have the opportunity to present to you my views on Titles III and VII of H.R. 9, the Job Creation and Wage Enhancement Act of 1995.

My name is Paul R. Portney and I am currently Vice President of Resources for the Future, an independent, non-partisan research and educational organization concerning itself with natural resources and the environment. It is important for me to note at the outset that the views I will present today are mine and mine alone. Resources for the Future takes no institutional position on legislative, regulatory or other public policy matters. Unlike other "think tanks," we have never been characterized as being Republican or Democratic, liberal or conservative. That is a distinction of which I am proud.

I am an economist by training and, since 1976, my research and policy analytic work has been concerned almost exclusively with regulatory issues, particularly those pertaining to federal environmental regulation. During this time, I spent nearly two years (1979-1981) as Chief Economist at the Council on Environmental Quality in the Executive Office of the President. One of my responsibilities then was to participate in President Carter's Regulatory Analysis

Review Group, an interagency team that regularly scrutinized proposed regulations emanating from both executive branch and independent regulatory agencies and made recommendations about how those proposed regulations might be improved. In large part because of that experience, I have paid particular attention over the last fourteen years to the series of efforts by four Presidents--two Democrats and two Republicans--to put in place and carry out a process of Executive Branch review of federal regulation. I will draw on the research, teaching, and thinking I have done about regulatory reform over this period of time in the comments I will make today.

Because I will focus most of my remarks on those aspects of Titles III and VII of H.R. 9 that trouble me, I want to take some pains to preface those remarks. First, let me say that I am as troubled by certain aspects of federal regulation--particularly environmental regulation--as I sense many members of this Committee are. Especially troubling to me are those provisions of regulatory statutes that prohibit regulators from even considering costs when making significant policy decisions. To choose but one example, albeit the most economically significant one in all federal regulatory law, Section 109 of the Clean Air Act, prohibits the Administrator of the Environmental Protection Agency from even considering economic costs as one factor in setting the National Ambient Air Quality Standards. Similar provisions exist in the Safe Drinking Water Act, Superfund, the Occupational Safety and Health Act, and other laws. *While economic impacts should never be allowed to predominate in*

*standard-setting for health, safety and the environment*, we simply cannot make rational federal environmental policy unless costs can be weighed in establishing the goals for policy in these areas.

I might add here that while regulatory reform statutes like H.R. 9 have a very useful role to play, they should generally not be viewed as a substitute for a statute-by-statute reexamination. This need not be done all at once; in fact, it would be better to conduct such a reexamination one statute at a time as they come up for reauthorization. Superfund and the Safe Drinking Water Act provide the first opportunities. This will give the members of Congress the opportunity to reflect carefully on the original rationale behind each of the statutes and the respects in which the passage of time and the accumulation of knowledge may have combined to suggest possibly different approaches.

Equally troubling in federal regulation are the technology-based requirements that often pop up, a recent example being the provisions of the 1990 amendments to the Clean Air Act dealing with hazardous air pollutants. Whether explicit or implicit, such requirements tend to freeze technology, ensure that pollution control costs are higher than they need to be and, consequently, handicap U.S. firms that must compete in international markets with firms in other countries that operate under less stringent or at least more enlightened regulatory regimes. Study after study has shown that giving regulated parties the flexibility to meet environmental, safety or health goals however best they see fit can reduce the cost of meeting those goals by 10-50 percent. Since we

currently spend in the vicinity of \$140 billion each year to comply with federal environmental regulations alone, these savings would be quite significant.

Titles III and VII of H.R. 9 deal prominently with the role of benefit-cost analysis in federal regulation, the subject to which I will confine my remarks today. Let me make clear my general beliefs about that role. Contrary to the views of many, I believe that benefit-cost analysis is a powerful analytical tool that can play a very useful role in public policymaking. It is my view that it has been consistently under- rather than overutilized by federal regulatory agencies, often--though not always--because Congress has constrained regulators in the latitude they have to consider such information.

Benefit-cost analysis can help illuminate cases in which regulatory proposals have not been carefully thought through. It can also, and has done so in the past, provide strong support for additional regulation--as in the case of the removal of lead from gasoline, and as in the case of the original 1970 amendments to the Clean Air Act. In addition, benefit-cost analyses done some years ago by my colleagues demonstrated convincingly that it made much more sense to leave both a free-flowing river and also a pristine wilderness area in their natural states rather than replace them with, respectively, a hydroelectric dam and a ski resort. Benefit-cost analysis, therefore, is inherently neither anti-environmental or anti-regulatory. As I will argue below, however, it is not a panacea, and for that reason we must be careful what burdens we impose upon it

My final prefatory remark pertains to the Committee's recent work.

Because I have recently written somewhat critically about certain provisions in an earlier version of the Job Creation and Wage Enhancement Act (Washington Post, January 15, 1995), I want to compliment the members of the Committee on the changes you have made in the revised version. To be sure, I still have serious reservations about a number of features in the bill. But if you continue to modify it as it makes its way through the House, and if subsequent changes are as constructive as those made recently, you will have initiated a debate that is long, long overdue and pointed the way toward constructive reform.

Having hopefully established my bona fides as a proponent of benefit-cost analysis, I want now to express concern about certain provisions of H.R. 9. For instance, Section 3201 (a) (5) (C) requires "A *certification* [emphasis added] that the rule will produce benefits to human health or the environment that will justify the costs incurred by local and State governments, the Federal Government, and other public and private entities as a result of implementation of and compliance with the rule..." It is not at all clear to me what such a certification entails. It is often the case in environmental benefit-cost analysis that using one set of health studies to estimate the risk reductions that will result from pollution reduction produces significant economic benefits. Using another set of studies--often as carefully done--suggests that the benefits of pollution control are much smaller, sometimes even non-existent. Similarly, on the cost side, estimates which make no allowance for technological improvement over

time in reducing pollution will come out much higher than those which forecast such improvement. (I should point out, incidentally, that I believe our current estimates of environmental compliance costs are too high because they ignore considerable "learning-by-doing" in pollution control that brings costs down with time.)

In a situation like this, where one plausible set of benefit and cost estimates suggests a favorable balance while another, equally plausible set suggests the opposite result, how would a regulator proceed? If this certification is interpreted as a requirement that the regulator say, "In my judgment, the benefits to society from going ahead with this rule will outweigh the costs," then I am comfortable with it. This is because, in my view, we will always have to rely ultimately on the judgment of the officials appointed to carry out regulatory responsibilities. If we do not agree with the judgments they make, the President should fire them. If the President stands by regulators who make unpopular decisions, that is why we have elections.

Let me anticipate one possible response to the issue I have just raised. Surely, you might argue, the risk assessment provisions embodied in H.R. 9 will eliminate the uncertainties inherent in estimating lives saved or illnesses prevented by pollution control, and thereby illuminate the "true" benefit of a regulatory proposal.. I do not believe this will be the case. While the provisions in H.R. 9 dealing with risk assessment can help bring some clarity and consistency to a muddled subject, they will simply never eliminate all

uncertainties. Thus, it will almost always be the case that a benefit-cost analysis will look favorable under one set of assumptions and unfavorable under another. While I believe firmly that in many such situations we can make judgments about the most likely outcomes, there will always be gray areas where even rigorous analysis points to no clear approach.

I do not mean to suggest that benefit-cost analysis can tell us nothing definitive. We have learned a great deal over the last twenty years for example about the values the public places on such things as reduced risk of death from accidents and illnesses, improved visibility in both national parks and in more ordinary settings, enhanced recreational opportunities, reductions in the incidence and severity of both acute and chronic illness, and even the existence of pristine areas that people may never visit but value nonetheless. Similarly, although I believe that estimating the costs of proposed regulations is much more complicated than many people believe, here too great strides have been made. For instance, we now realize that the true economic costs associated with regulation must be measured only after the initial expenditures incurred have reverberated throughout the economy and have manifested themselves as higher product prices, reduced earnings, job losses (and sometimes job gains), and so on. Similarly, we are doing better at taking account of cost-reducing technological change, although we need much more work on this subject.

Nevertheless, despite this real progress, we are still some ways away from the point at which we can confidently make precise estimates of benefits

and costs, particularly for programs that result in aesthetic improvements or ecosystem protection. The required certification in Section 3201 (a) (5) (C) will be no more than a means to prevent any regulation--good or bad--if it is interpreted as requiring conclusive "proof" that benefits exceed costs. It is very important that the Committee clarify this language and realize that, ultimately, there is no substitute for good judgment on the part of regulatory officials.

On less pressing matters, Section 3201 (c) (1) suggests that both "direct and indirect" costs be taken into account for the purposes of the benefit-cost requirements. Presumably, indirect costs are those incurred by parties who are not regulated directly, but who ultimately bear economic burdens as a result of regulation elsewhere. (For instance, regulations falling initially on electric utilities will have significant impacts on aluminum producers because the latter use a great deal of electricity.) In addition, I presume that indirect costs might also include the imputed value of people's time spent waiting to have a car inspected, or waiting to get a permit.

It is perfectly reasonable to include such indirect costs in a benefit-cost study. Indeed, failing to include such costs could give regulators an incentive to shift costs from those directly imposed to those imposed more circuitously. But if indirect costs are to be taken into account, so too must indirect benefits.. For instance, air pollution controls that protect a forested area not only benefit the owner of the forest, but also those who might pass by it regularly and enjoy its scenic beauty. Failure to include such benefits as this would bias downward the

benefit-cost ratio in a regulatory analysis, in the same way that ratio would be biased upwards if all costs were not counted. I would like to see the language in the bill reflect this symmetry.

Let me turn now to Title VII of the bill, which spells out the requirements that the economic analyses must meet. I have several observations to make. First, Section 7004 (b) offers a different definition of "major rule" than that offered in Section 3201 (c) (2). I strongly urge the Committee to use the latter rather than the former definition. My educated guess is that using the much lower threshold for a major rule (defined in Section 7004 (b) as a rule that affects 100 persons or more, or that requires the expenditure of \$1,000,000 by any person) will expand by about ten-fold the number of regulations for which benefit-cost analyses must be done. Since many of these regulations could truly be considered minor, there is little to be gained by bogging regulatory agencies down with analytical requirements. Much better to concentrate their attention on the regulations that have really significant economic impacts.

The one caveat to my recommendation here involves possible "unbundling" of regulations by agencies. If it turns out that, in an effort to evade the requirements to do careful analysis in support of rules, agencies break major rules down into separate pieces and issue them individually, it may be necessary to lower the threshold for analysis. Until and unless that is seen to be the case, however, the definition in Section 7004 (b) (2) is not only inconsistent with the earlier definition, but also unwise.

In my view, by far the most controversial provision in the Job Creation and Wage Enhancement Act of 1995 is Section 7005. Interestingly, I have heard relatively little discussion of this provision to this point. In its entirety, the provision states "An agency may not adopt a major rule unless the final Regulatory Impact Analysis is approved in writing by the Director of the Office of Management and Budget or by an individual designated by the Director for that purpose."

Whether intentionally or not, this provision would give the Director of OMB de facto control over the entire federal regulatory apparatus. It would, in other words, make him or her the Director of Federal Regulation as well as the Director of the Office of Management and Budget. And because of the uncertainties and--yes--value judgments that will always characterize both benefit-cost analysis and quantitative risk assessment, it will always be possible to find fault with a Regulatory Impact Analysis. Evidence that convinces a regulatory agency head that benefits are likely to exceed costs may not be convincing to the Director of OMB. Evidence that convinces the regulator that the proposed approach is the least expensive may not be convincing to the Director of OMB. Such statements could be made for many of the requirements that Regulatory Impact Analyses would have to meet under Section 7004 (c).

Thus, while I am an avid supporter of the increased use of benefit-cost analysis and other analytical techniques in regulatory decision-making, while I am quite critical of a number of rules issued by federal regulatory agencies, and

while I believe that a President must have an effective regulatory oversight operation within the Executive Branch, I am concerned by the power this provision would give to the Director of OMB. Far better, it seems to me, to give our regulators the statutory mandate to balance carefully the pros and cons associated with proposed rules, as well as the resources necessary to conduct the requisite analyses, and then hold them strictly accountable for the decisions they make.

This concludes my prepared remarks. Thank you again for giving me the opportunity to appear before you. I will be happy to answer any questions you may have.

The CHAIRMAN. Thank you very much.

Mr. McGarity.

Mr. MCGARITY. Thank you very much, Mr. Chairman. I am pleased to be here to testify about Title III of the Job Creation and Wage Enhancement Act. I would like to spend the bulk of my time talking about two aspects of the statute that concern me. One is the requirement for comparative risk assessment and the other is the various opportunities for judicial review.

I have some general concerns that I have raised in my testimony, my prepared testimony, and I would hope that that would be entered for the record. But that is what I would like to focus in on.

The CHAIRMAN. In all cases, the full text of your remarks will be included in the record. And you know, feel free to summarize in a way that you think best makes your point.

Mr. MCGARITY. Thank you. The provisions on comparative risk assessment raise some real concerns in my mind because of the possibility of inappropriate comparisons being made as, for example, between the risks that we voluntarily assume and risks that others impose on us.

The difference in disease end points I think make comparative risk assessments to some extent inappropriate. There are various instructional considerations that generally get ignored in comparative risk assessments as well as generational distributional reassignments, if you will, occasionally as well.

I worry because I hear Ms. Goldman talk about the fact that we don't incorporate lots of benefits information into our risk assessments so that the risk assessment if one starts comparing them with other risks or with benefits are already sort of biased against those things that can't be incorporated into the risk assessments, the tendency of risk assessors—I think to what Professor Tribe said—dwarf soft variables. They can't be quantified, so they don't get included.

And that is related to a concern, with all due respect to the people around me here, that experts tend to take over the risk assessment project. And I think it elevates their views about the various policies that underlie some of the assumptions that go into risk assessment over the public views of appropriate policy.

Let me speak specifically to judicial review because I am familiar with judicial review from my work. I think that there are several places here where under existing doctrines under the Administrative Procedure Act by adding these substantive requirements, judicial review will be facilitated.

First, I think that the only thing that is standing in the way between—or in the way of prepromulgation of judicial review of a risk assessment, that is the risk assessment that is written prior to the promulgation even of the proposed rule—the only thing that is standing in the way of that is a fairly loose doctrine of ripeness. And I think plausible cases can be made that a risk assessment itself may have enough impact to be ripe for judicial review.

Certainly after the promulgation, we will see these risk assessments given to the criteria in the proposed statute are scientific, we will see attacks launched at risk assessments as well as at the substance of the rule. I don't think the courts are competent to be

resolving these kinds of disputes. And I think we have to be careful because it cuts both ways.

There are risk assessments in environmental impact statements that agencies provide that I take it would just add another claim to a NEPA case based on the adequacy of an EIS. Now, the adequacy of the risk assessment would be just one additional claim there.

The cost benefit analysis portions of the bill likewise provide the possibility of judicial review. Here I think a very good case could be made for judicial review of the failure to prepare a cost benefit analysis. The statute says you shall prepare a cost benefit analysis for a major rule. If the agency declines to do so, I think that a very good case, just as in the environmental impact assessment legislation and litigation, we could see claims filed in court for judicial review of the failure to prepare a cost benefit analysis. You could likewise, I think, see the similar sorts of claims raised on the merits directed toward the adequacy of the cost benefit analyses.

I share Dr. Portney's problems with the certifications. I see it from a somewhat different angle because I see these certifications as a subtle attempt to repeal by implication technology-based provisions in most of our statutes. I don't see how an administrator could in honesty certify that the benefits of many technology-based standards outweigh the risks because that is not just what technology-based standards are about. We don't analyze them from that perspective.

And if I were an administrator, I would be very disinclined to—I don't know what the penalty is for false certification, but I would be worried enough that when the statute told me to provide a standard that requires the best available technology, I would have a hard time making a certification that that standard benefit outweighed its risks.

With respect to peer review, I just have a couple of comments. The most important one I think is the additional burden that that could cause on the rulemaking process.

I think that the agency will have to treat peer review as an entirely ongoing process. That it is really not complete until all outside comments have been reviewed by the peer review panel. And I think that will shape the process considerably.

It is not at all clear to me that we have enough people out there, given the lowered thresholds now for peer review, that we have got enough competent scientists out there to do all of these peer reviews. The prestige factor is going to drop I think considerably as we have so many more panels being established and we are not paying these people.

I have written an article on peer review in the National Science Foundation. I don't understand why these people do it in the context of the National Science Foundation grants. It is a gratis volunteering of their time. Why they would do it for the Environmental Protection Agency gratis is beyond me.

In conclusion, I think that the bill is kind of a brute force blunt instrument. I think that it attempts to bludgeon the Federal Government into less—into being a less aggressive protector of consumers, workers, and the environment. If Congress doesn't want the agencies to write the regulations, then they should amend the

substantive laws, the Clean Air Act, the Clean Water Act, and not do it indirectly through a process that's going to deprive the agencies of the wherewithal to write the rules necessary to implement this legislation.

Thank you.

[The prepared statement of Mr. McGarity follows:]

TESTIMONY OF

THOMAS O. MCGARITY  
W. James Kronzer Chair in Law  
University of Texas School of Law

on

Title III of H.R. 9

The Job Creation and Wage Enhancement Act

United States House of Representatives  
Committee on Science

February 3, 1995

My name is Tom McGarity. I hold the W. James Kronzer Chair in Law at the University of Texas School of Law, where I teach courses in Administrative Law and Environmental Law. In the early 1980s, I conducted a study for the Administrative Conference of the United States (ACUS) on "The Role of Regulatory Analysis in Regulatory Decisionmaking." That study resulted in ACUS Recommendation 85-2: Agency Procedures for Performing Regulatory Analysis of Rules. After conducting further research on the use of regulatory analysis in the federal government, I published a book on that subject entitled *Reinventing Rationality: The Role of Regulatory Analysis in the Federal Bureaucracy* (Cambridge Univ. Press 1991). I have also written articles on risk assessment and risk management in the federal government. I am, therefore, very pleased to testify on Title III of the proposed Job Creation and Wage Enhancement Act.

If enacted as is, I am convinced that the proposed statute will bring about radical changes in the way that federal agencies go about writing and implementing the regulations that are needed to protect consumers, workers, and the environment. These changes will not come about through a careful, systematic and open debate over whether Congress should repeal or amend the consumer, worker safety and environmental that Congress enacted during the 1960s and 1970s and strengthened during the 1980s and early 1990s. Rather, the proposed Act will effectively repeal these protective statutes through the back door by making it impossible for the agencies that are assigned the task of implementing the laws to do their jobs.

#### **Risk Assessment.**

Section 3401 requires agency risk assessments to follow certain risk assessment principles that are by-and-large uncontroversial descriptions of the contours of a good risk assessment. While it is unlikely that enactment of the Bill will change current agency practice significantly, it does have the potential to "freeze" the very fluid science of risk assessment at its existing level of sophistication and prevent growth into heretofore unanticipated directions. Qualifiers like "to the extent feasible," which appear frequently in section 3105, should appear more often in section 3104.

#### **Centralized Risk Assessment.**

Section 3106 requires the President to issue guidelines to federal agencies consistent with the risk assessment and characterization principles specified in the Bill. Promulgating centralized risk assessment principles looks like a good idea in principle, but it can result in imposing risk assessment policies on agencies that are contrary to what their statutes require. Policy plays an important role in assessing risks, as well as in managing

risks.<sup>1</sup> The Bill assumes that it is appropriate to resolve those policy questions the same way in every statutory context. If, however, the statutory policies underlying one statute are more risk averse than the policies underlying another, it may be inappropriate to apply the same risk assessment policies to risk assessments under both statutes.

#### **Retrospective Risk Assessments.**

The additional requirement that agencies re-examine previously published risk assessments has the look of a make-work requirement designed to tie up agency resources with unproductive analytical exercises. If an existing rule is based on outdated information and should therefore be changed, interested parties are free to petition the agency under section 553(e) of the Administrative Procedure Act,<sup>2</sup> and the agency must either initiate a new rulemaking or explain why a fresh rulemaking is unnecessary.<sup>3</sup> But to require agencies to re-examine old risk assessments just for the sake of re-evaluating them is extremely wasteful of scarce agency resources.

#### **Best Estimates.**

Section 3105 requires agencies to provide "best estimates" of health and environmental risks along with more common "worst case" predictions. When a risk assessment purports to provide a "best estimate," however, it is especially important that it also present an honest portrayal of the assumptions that went into that assessment and of the huge uncertainties that ordinarily surround single point estimates of risk. This exercise will usually reveal that the best estimate is really a haze of predictions, no one of which bears any clear relation to reality. The Bill might greater honesty on the part of risk assessors if instead of a best estimate, it required a "range of most probable risks."

#### **Substitution Risks.**

The requirement that agencies provide a statement of "substitution risks" when information on such risks has been provided to the agency could result in highly speculative and wasteful exercises in most statutory contexts, because regulatory agencies are rarely empowered to require the substitution of one activity or technology for an existing activity or technology. Since regulatees are ordinarily free to meet specified

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<sup>1</sup> National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (1983). See also Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 *Yale J. on Reg.* 89 (1988).

<sup>2</sup> 5 U.S.C. § 553(e).

<sup>3</sup> 5 U.S.C. § 555(e).

limitations by any means they deem proper, it is often difficult for agencies to predict in advance how the regulated entities will react. Section 3105(a)(4) should be amended to require agencies to address substitution risks only where it is feasible to do so, given the nature of the regulatory action and the availability of relevant information.

### **Comparative Risk Assessment.**

The most troublesome aspect of section 3105 is the requirement that agencies engage in comparative risk assessment. For several reasons, the Committee would be well-advised to delete this requirement from the Bill.

First, the uncertainties that becloud risk assessment also render such comparisons extremely fuzzy. The Bill assumes that existing estimates of risks that are familiar to and routinely encountered by the general public can be confidently displayed in an understandable fashion. This is simply not true. The risks involved in familiar activities are not always easily calculated, and when they are, they are not easy to state in a comprehensible way.

Second, the "familiar" risks that risk assessors use for comparison purposes are risks that people voluntarily encounter, like the risk of getting killed playing golf on a cloudy day. Most people find it inappropriate to compare such risks to the risks that regulators are attempting to prevent large industrial facilities from imposing on their workers or their neighbors. To force the comparison is to endorse a public policy of treating such risks in an equivalent way, and this is entirely inappropriate.

Third, comparative risk assessment cannot legitimately be used to compare activities that result in different disease end points. Comparisons between risks to human health and risks to ecosystems or endangered species are likewise suspect. Such comparisons lack any common denominators.

Fourth, comparative risk assessment tends to ignore important distributional considerations. It is not clear that society should give greater regulatory attention to an activity that poses a very low probability risk to a large number of people than it gives to an activity that poses a very high probability risk to an isolated minority of individuals (e.g., sickle cell carriers), even if an objective risk assessment concludes that the overall risk of the first activity is twice that of the latter.

Fifth, comparative risk assessment fails adequately to account for generational equity. Is it appropriate to say that society should not address activities that pose a low risk to future generations because we are presently willing to tolerate higher risks to ourselves? A comparative risk assessment subtly suggests that we may impose risks on future generations so long as we are willing to tolerate risks of equal magnitude.

Sixth, comparative risk assessment tends to discourage the "leaps of faith" that are sometimes required to move technologies to new levels or to change the production processes that result in pollution. The "source reduction" approach does not rely upon sophisticated attempts to compare existing risks with the risks that may result from the implementation of alternative source reduction strategies. Risk assessment does have a role, but it is the relatively unsophisticated one of evaluating whether likely substitutes are more risky than the processes that they replace.

Seventh, comparative risk assessment tends to belittle information and values that cannot easily be incorporated into the risk assessments. When information or values arise that cannot easily be factored into the risk assessment models, the modelers tend to ignore them. Yet these unquantifiable aspects of environmental decisionmaking are often the most important to the public.

Eighth, comparative risk assessment elevates the views of experts over public perceptions of risk. Some professional risk assessors are inclined arrogantly to dismiss the fears of ordinary people who are actually exposed to risk and to blame the news media and environmental groups for stirring up public anxiety. Comparative risk assessment is often invoked by professional risk assessors to "educate" a public that is advocating a "misguided" policy. Yet the simplifying assumptions that professional risk assessors build into their models often reflect their own policy preferences.

Section 3105(a)(3) does contain the qualifying language "[t]o the extent feasible," but that misses the point of the foregoing discussion. A comparative risk assessment may be entirely feasible and altogether inappropriate. At the very least, the language should be modified to insert the words "and appropriate" after the word "feasible." Better still, Congress should decline to endorse this potentially misleading approach to portraying the risks addressed by health and environmental regulation.

### **Judicial Review.**

The risk assessment provisions of Title III are silent on the question whether an allegedly adversely affected party may seek judicial review of the contents of a risk assessment. A party who disagrees with the contents of a risk assessment may desire an opportunity to persuade a court that the agency's risk assessment does not comport with the statutory criteria in sections 3104 and 3105. Since the statute is silent on the question of judicial review, the only thing standing in the way of immediate judicial review of final risk assessment is the judicial doctrine of "ripeness." The agency would probably argue that the issues concerning the adequacy of risk assessments will not be ripe for judicial resolution until the agency has promulgated a final rule, at which time the arguments can be made as

additional claims in a general challenge to the regulation under the "arbitrary and capricious" test. It is not clear that all courts would agree. If a regulatee (or perhaps a public interest group) could plausibly argue that the risk assessment by itself will have an immediate and tangible impact on its legitimate interests, a court might be persuaded to entertain a challenge to the risk assessment prior to any other agency action.

In any event, the specific requirements in section 3104 and 3105 clearly provide "law to apply" in a post-promulgation challenge to the agency rule. In addition to the familiar arguments concerning the record support for the agency's action in the rulemaking record, courts can expect to see particular claims aimed at the adequacy of the risk assessments under the criteria articulated in sections 3104 and 3105. While this additional litigation will provide more grist for the lawyers, it is not likely to serve the broader public interest. Courts are not capable of resolving highly technical disputes about whether particular risk assessments measure up to these statutory criteria.

Section 3103(b) says that the risk assessment and risk characterization principles are applicable to "all risk assessments and risk characterizations prepared by, or on behalf of, any Federal agency in connection with Federal regulatory programs designed to protect human health, safety, or the environment." The requirements would therefore apply to risk assessments performed in connection with environmental impact statements prepared under the National Environmental Policy Act for major federal actions significantly affecting the quality of the human environment. The principles could provide a basis for additional judicial challenges to EISs. For example, an environmental group might challenge a risk assessment prepared in connection with a Forest Service decision to allow additional spraying of a pesticide on soon-to-be-harvested timber. Just as judicial review of risk assessments has the potential to delay rulemaking intended to protect public health and the environment, it could also slow down agency actions aimed at speeding up development of federal (or even private) resources.

To avoid a whole host of unanticipated consequences, a new section should be added to Title III that precludes judicial review of risk assessments except insofar as the issues raised are relevant to challenges to the substance of the underlying regulations.

### **Cost/Benefit Analysis.**

Despite a vast and growing literature exists on the practical and theoretical limitations of cost/benefit analysis, section 3201 requires agencies to prepare a cost/benefit analysis for "each major rule designed to protect human health, safety, or the environment." A major rule is defined specially for this purpose to be one that will have an "annual effect on the economy of \$ 25,000,000," result in a "major increase in costs or

prices," or have "[s]ignificant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets."

### **Practical Problems.**

Cost benefit analysis faces a host of practical problems in locating and analyzing relevant data. Given the huge uncertainties that plague both cost and benefit assessments, no honest analyst using existing data and analytical techniques can claim the ability to locate a single point where the incremental benefits of a regulation just exceed its costs.

### **Valuation Problems.**

More important are the theoretical and moral objections to cost/benefit analysis. Perhaps the most important is the much-discussed inability of economic analysis to reduce environmental benefits, such as human life and endangered species, to dollar amounts for purposes of comparisons with regulatory costs. Many critics of cost/benefit analysis argue that reducing the value of life to a dollar amount belittles life's intrinsic value. This highly reductionist form of analysis suggests that society should be indifferent to a choice between a live human being and a check payable to the public treasury in some amount, a notion that is morally repugnant in a society that purports to value human life.

For very highly valued things that are not traded in markets, cost-benefit analysis is at its core "incoherent" or "schizophrenic," because it cannot yield a single numerical value. The value of a thing can be measured either by the willingness of the purchaser to pay for it or the willingness of the seller to sell it. For objects that are not traded in markets, these two measures are not necessarily the same. For example, the price at which a person might sell his heart (under the willingness to sell measure) probably exceeds the price at which he is prepared to pay for it (under the willingness to buy criterion). The latter measure depends upon the resources available to the person; the former measure is limitless. Cost-benefit analysis using the "willingness to pay" measure is thus biased against governmental intervention, and the bias grows as the interest to be protected increases in value.

### **Bias Against the Future.**

A further bias against future generations is introduced by the generally adopted practice of discounting future benefits to present value. OMB has traditionally insisted that agencies use a very high discount rate of 10 percent in calculating the benefits of health and environmental regulations. At a discount rate of 10 percent, a dollar's worth of benefits 50

years from now is worth slightly less than a penny today.<sup>4</sup> This means that the benefits of a regulation that would prevent catastrophic loss in 50 years are likely to be outweighed by even modest present costs.

### **Distributional Concerns.**

Cost/benefit analysis is deaf to distributional considerations. Cost/benefit analyses often argue strongly against regulatory actions based primarily upon distributional considerations, even though they are often at the core of regulatory statutes.

### **Anti-democratic Tendencies.**

Cost/benefit analysis can exacerbate the elitist tendencies of risk assessment by substituting the analyst's valuation criteria for the ethical and political judgments that are embodied in the legislation that was enacted by a democratically elected legislative body. When analysts attempt to hide their own policy preferences behind the veneer of scientific objectivity, they are behaving as political actors and their cost/benefit analyses should be treated as such.

### **Inconsistency with Existing Statutes.**

The Bill's requirement that agencies engage in cost/benefit analysis runs counter to the many provisions in health and environmental statutes that preclude the use of cost/benefit analysis. The Supreme Court has held that the Occupational Safety and Health Act precludes cost-benefit analysis in setting health standards,<sup>5</sup> and the D.C. Circuit has held that EPA may not consider costs in promulgating National Primary Ambient Air Quality Standards.<sup>6</sup> It is not clear how the courts would interpret the apparent conflict between the prohibition on the use of cost/benefit analysis in existing statutes and the Bill's explicit command that the President require cost/benefit analysis for major rules. It is certainly conceivable that the courts would find that the more recently enacted statute should prevail.<sup>7</sup> Thus, the Bill might effectively repeal the provisions in earlier enacted statutes that prohibited agencies from considering cost/benefit analysis.

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<sup>4</sup> M. Russell, "Discounting Human Life" (Or, The Anatomy of a Moral-Economic Issue), 82 Resources 8 (1986).

<sup>5</sup> American Textile Manufacturers Inst. v. Donovan, 452 U.S. 490 (1981).

<sup>6</sup> Lead Industries Association v. EPA, 647 F.2d 1130, 1148-51 (D.C. Cir. 1980) and American Petroleum Institute v. Costle, 609 F.2d 20 (D.C. Cir. 1979).

<sup>7</sup> Section 3103 contains the following savings clause: "Nothing in this subtitle shall be construed to modify any statutory standard or requirement designed to protect health, safety, or the environment." Sections 3201 and 3301 do not contain similar savings clauses.

### **Inconsistency with Regulatory Negotiation.**

On an even more practical level, the cost/benefit analysis requirement may discourage agencies from engaging in collaborative agency processes like regulatory negotiation. Sometimes an agreement can be fashioned among the affected parties that allows a regulation to go into effect, even though it does not meet the strict cost/benefit criteria laid out in section 3201. Indeed, the mere existence of the cost/benefit requirement may discourage affected parties from entering into the negotiations.

### **Expense.**

For all of its inadequacies, cost/benefit analysis is very time consuming and expensive. The Bill contemplates a full-blown analysis of the costs and benefits of the regulation that the agency promulgates and of all significant alternatives to that regulation.<sup>8</sup> In the past, the cost/benefit analyses for major rules have cost millions of dollars apiece, and they have consumed years of precious agency time. The benefit to society of these mammoth efforts was open to serious question when they were limited to federal actions having an impact of \$100,000,000. The Bill would greatly expand the cost/benefit analysis requirement to all rules with an impact of \$25,000,000, plus all rules that could result in a major increase in costs or prices and all rules that might have significant adverse effects on competition, employment, investment, etc. This expansive change in the threshold test for determining when a cost/benefit analysis must be prepared will enormously increase the number of rules subject to this burdensome requirement.

### **III-Defined Threshold Factors.**

The subjective threshold tests set out in subsections 3201(c)(2)(B) and (C) should greatly increase the uncertainty about whether particular rules require a cost/benefit analysis. What is a "major increase" in prices or costs if it is not measured by some dollar amount? "Significant adverse effects on competition, employment, investment, productivity, innovation, or [foreign competition]" are all highly speculative indirect effects of regulation. How can the agency possibly know whether a rule passes this threshold without performing an analysis of costs, prices, and domestic economic impact?

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<sup>8</sup> Section 3201(a)(1) requires the agency to produce for every "proposed or promulgated rule, an assessment of incremental costs and incremental risk reduction or other benefits associated with each significant regulatory alternative considered by the agency in connection with the rule or proposed rule." In addition, the section 3201(a)(5)(D) certification "that there is no regulatory alternative . . . that would achieve an equivalent reduction in risk in a more cost-effective manner" presupposes that the agency has performed a cost-effectiveness analysis on all regulatory alternatives allowed by the statute. Either or both of these assessments will be very resource intensive.

### Judicial Review.

Affected parties will no doubt seek judicial review of agency failures to prepare cost/benefit analyses under the Administrative Procedure Act, which permits reviewing courts to set aside agency actions that are "without observance of procedure required by law."<sup>9</sup> An aggrieved party could easily make the case that the cost/benefit analysis is a procedure required by law.<sup>10</sup> If the agency decides to prepare a cost/benefit analysis for a rulemaking initiative, it can plan to spend millions of dollars and many months or years in the effort. If it declines to prepare a cost/benefit analysis, it must be prepared to defend that action in court. In either case, the result is the same: delay in the implementation of the agency's statutory obligations. These exceedingly burdensome requirements will give new meaning to the phrase "paralysis by analysis."

Once the cost/benefit analyses have been prepared, parties will no doubt seek judicial review of their contents. As discussed previously in connection with judicial review of risk assessments, such challenges may conceivably be entertained even prior to the promulgation of the final rule. In any event, absent preclusion of judicial review, the specific requirements of section 3201 will no doubt provide the grist for separate claims directed at the cost/benefit analyses when a final rule is challenged in court. Once again, the courts are not qualified to resolve such highly technical disputes.

### Problems with Certifications.

The section 3201(a)(5)(B) and 3201(a)(5)(C) certifications appear to be subtle attempts to undermine the technology-based approach that currently dominates many of the environmental statutes. Section 3201(a)(5)(B) would require the agency to certify "that the rule will substantially advance the purpose of protecting human health or the environment," and section 3201(a)(5)(C) would require a certification that "the rule will produce benefits to human health or the environment that will justify the costs." Both of these certifications may be impossible to make in the context of technology-based standards, and they would in any event entail just the kind of analysis that the technology-based provisions of the health and environmental statutes were intended to avoid.

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<sup>9</sup> 5 U.S.C. § 706(2)(D).

<sup>10</sup> Recent case law, however, raises the question of who would have standing to press the claim that the agency should prepare a cost/benefit analysis. See *Lujan v. Defenders of Wildlife*, 112 S.Ct. 2130 (1992). A company subject to the rule that could result from the rulemaking action has at least a fair chance of convincing a court that it has standing to challenge the failure to prepare a cost/benefit analysis, much as environmental groups have standing to challenge the failure of an agency to prepare an environmental impact statement.

If an environmental agency could not honestly certify that the benefits of a technology-based standard would justify its costs, would it be prohibited from promulgating the rule? If it promulgated the rule without the certification, it is certainly conceivable that an affected party would ask a court to remand the standard until the agency complied with the explicit certification requirement, in which case the rule would remain forever in limbo.

It may be that Congress no longer believes that technology-based standards are appropriate vehicles for addressing health and environmental risks. If Congress no longer means to implement the approach that currently dominates many health and environmental statutes, it should forthrightly initiate the process of amending those statutes, rather than attempt accomplish that result in a backdoor fashion through certification requirements.

#### **Peer Review.**

Section 3301(a) requires all agencies protecting health, safety or the environment to establish a program for peer review of risk assessments and economic analyses for major rules. Peer review is a useful adjunct to scientific rulemaking. The scientific community has a long tradition of relying upon peer review in bestowing the rewards (grants, publications, etc.) that science has to offer its practitioners. Even though agencies are supposed to be repositories of expertise, most agencies feel constrained to seek neutral advice from outside scientists. Peer review by outside experts can enhance the competence of the agency's technical judgments, while at the same time deflecting criticisms from outsiders.

#### **"Stacking" Peer Review Panels.**

One very important aspect of peer review is "balance," which is required by section 3301(a). Unfortunately, despite a similar requirement for balance among appointees to federal advisory committees in the Federal Advisory Committee Act, agencies are generally able to "stack" advisory committees with persons whose opinions on the relevant questions can be relatively easily predicted, thereby ensuring that the panel will reach a predetermined outcome. Although peer review panels normally attempt to achieve consensus before providing advice, section 3301(c) empowers a majority of the committee to determine what considerations were appropriate in the risk assessment. This would allow the agency to stack a committee by appointing a majority with a known point of view, while allowing token representation of opposing points of view.

#### **Delegation of Decisionmaking Power to Peer Review Panels.**

Since the peer review panel's report would be part of the record on judicial review, the agency would ordinarily be extremely reluctant to go forward with a rule reflecting an

assessment of the data that varied from that of the peer review panel. The Bill would thus to some extent turn health and environmental decisionmaking over to the experts by giving a majority of any risk assessment panel the power effectively to veto any risk or cost assessment.

#### **Additional Burden and Delay.**

Section 3301(b) requires peer review for "scientific and economic information used for purposes of any [cost/benefit] evaluation." In addition section 3201(a)(5)(a) requires an agency to certify that its cost/benefit analysis incorporated "significant and relevant information provided to the agency by interested parties," and that such outside information undergo peer review. As a practical matter, the agency will have to treat peer review as an ongoing process that is not complete until all outside comments have been reviewed by the peer review panel. In addition to adding another step to the rulemaking process, peer review of outside comments will place additional burdens on the peer reviewers. Since commenters nearly always wait until the end of the comment period to comment, this extra step will normally delay the promulgation of rules.

The agency is required by section 3301(d) to provide a written response to all significant peer review comments. This additional burden of explanation will cause even further delays in the rulemaking process. Agency employees must spend time selecting outside reviewers and staffing advisory committee meetings. The busy scientists who serve on these committees must be given generous amounts of time to complete their reviews and incorporate their evaluations into reports to the agency. Peer review panels frequently recommend that agencies refrain from regulating until they have obtained more information on one or more critical points. An agency that wants to act expeditiously can reject an advisory committee's requests for additional data only if it is willing to go through the time-consuming exercise of explaining its reasons for doing so.

#### **Insufficient Pool of Peer Reviewers.**

Section 3201(a)(5)(A) applies to all major rules. Section 3301(f) defines term "major" to include all rules with an impact of greater than \$100,000,000. But it also includes all rules that could result in a major increase in costs or prices and all rules that might have significant adverse effects on competition, employment, investment, etc. It is not at all clear that the scientific community is capable of providing knowledgeable peer reviewers for such a large number of rules. The statute is silent on whether peer reviewers will be paid for their efforts and, if so, how much. At present the number of scientific advisory panels is small enough that it is considered prestigious to be asked to sit on such a panel. Greatly expanding the range of rules subject to peer review will no doubt dilute the

prestige of being on such a panel and, correspondingly, the willingness of top-notch scientists to serve on such panels. The remaining pool of available and willing scientists will no doubt be dominated by scientists who are on the payrolls of the regulated industries, and section 3301(a)(3) prevents the agency from declining these scientists solely because of their obvious conflict-of-interest.

### **Existing Peer Review Vehicles are Adequate.**

The relevant agencies already have scientific review mechanisms in place to review risk and economic assessments. Sometimes this is required by the agency's statute,<sup>11</sup> but even when not required, the agencies usually make use of some form of peer review in important rulemaking initiatives. This whole subtitle is therefore largely redundant and should therefore be abandoned on the sound presumption that "if it ain't broke, don't fix it."

### **Conclusion.**

By brute force, the analytical provisions of Title III of the Job Creation and Wage Enhancement Act will allow large corporations, small businesses and individuals to bludgeon the federal government into a much less aggressive protector of consumers, workers, and the environment. Because its anti-government tools are much more accessible to large corporate entities than individuals, however, the Bill is really a vehicle for powerful economic interests to expand their power over the less powerful individuals who are supposed to be protected by the federal laws that Congress has enacted over the last three decades.

If Congress does not want the agencies to write regulations aimed at protecting consumers, workers, and the environment, then it should amend the substantive statutes to provide explicit guidance as to which protections should be reduced or eliminated. There should be a public debate about the need for particular protections, and legislators should be accountable to the electorate for their votes on substantive revisions to the statutes that currently protect consumers, workers and the public in general. The Bill's overwhelmingly burdensome analytical requirements will effectively amend the statutes by ensuring that the agencies will not have the wherewithal to write the rules necessary to implement the legislation that Congress has enacted.

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<sup>11</sup> See 42 U.S.C. § 7417 (1983) (Clean Air Scientific Advisory Committee); 42 U.S.C. § 7409 (1983) (special scientific advisory committee for reviewing National Ambient Air Quality Standards); 7 U.S.C. § 136w(d) (West 1991 Supp) (pesticides scientific advisory committee).

## Curriculum Vitae

**THOMAS O. MCGARITY****Education**

- Undergraduate      Rice University (B.A. 1971)  
                              Physics Major  
                              Instrument Society of America Scholar  
                              (Junior and Senior years)
- Law School            University of Texas (J.D. magna cum laude 1974)  
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                              Chancellors (top 2% of graduating class)

**Employment**

- Law Clerk to Judge William E. Doyle (1974-75)  
 United States Court of Appeals  
 Tenth Judicial Circuit  
 Denver, Colorado
- Attorney Advisor (1975-77)  
 U.S. Environmental Protection Agency  
 401 M Street S.W.  
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- Associate Professor of Law (1977-1980)  
 University of Kansas School of Law  
 Lawrence, Kansas
- Professor of Law (1980-1985)  
 University of Texas School of Law  
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- Cooper K. Ragan Professor of Law (1985-1986)  
 University of Texas School of Law  
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- William Stamps Farish Professor of Law  
 (1986-1994)  
 University of Texas School of Law  
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- W. James Kronzer Chair in Trial and Appellate Advocacy  
 (1994-present)  
 University of Texas School of Law  
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## Publications

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### Advisory Committees, Consulting, Etc.

Consultant, Administrative Conference of the United States, 1979-80 (project on races to the courthouse)

Member, Advisory Panel on Occupational Genetic Testing, Office of Technology Assessment, United States Congress, 1981-82

Consultant, Administrative Conference of the United States, 1983-85 (project on regulatory impact assessment in the federal government)

Member, Committee on Multimedia Approaches to Pollution Control, National Research Council, National Academy of Sciences, 1985-present

Consultant, Administrative Conference of the United States, 1986-88 (project on Occupational Safety and Health Administration Decisionmaking)

Consultant, Administrative Conference of the United States, 1989-93 (project on approaches to reducing bias in awarding discretionary grants)

Consultant, Administrative Conference of the United States, 1989-present (project on implementation of the HUD Reform Act)

Consultant, Carnegie Commission on Science, Technology and Government, 1990-present (project on alternative approaches to scientific and technical rulemaking)

Member, Environmental Protection Agency, National Enforcement Training Institute Advisory Council, 1991-present

The CHAIRMAN. Thank you very much.

Where am I going next here? Okay. To Dr. Yosie.

Mr. YOSIE. Thank you, Mr. Chairman.

As a participant in the risk assessment process for the past 17 years, first as director of EPA's Science Advisory Board, later as a vice president of the American Petroleum Institute, and now in my current capacity, I've personally concluded that the opportunity to enact workable risk assessment legislation has never been better, and should be seized.

I believe that Congress should attempt to resolve at least four basic issues that have hampered a more effective use of risk assessment in the past two decades. First is the need to apply risk assessment as a strategic planning tool in regulatory agencies, to ensure that health, safety, and environmental priorities are more appropriately chosen commensurate with society's understanding of real and potential risks. When risk assessment is used in this fashion, Congress and the public at large will be in a better position to evaluate the effectiveness of environmental programs. Each new appropriation cycle will thus provide both the legislative and the executive branches the opportunity to compare the seriousness of various risks and evaluate the performance of programs designed to reduce risks.

Second major issue, I believe, is before Congress, is to ensure that high-quality risk assessment data is more expeditiously and completely used in risk assessment. A major part of the current debate relates to the concern that regulatory agencies have been too slow in substituting scientific data in lieu of certain assumptions and models. I believe that Congress should authorize peer review panels to advise when new scientific information is of sufficient quality and relevance to use in policy-making.

Third, Congress should improve the peer review process and should be guided by the following principles: First, peer review should focus on the scientific basis of decision-making and should not attempt to intermingle scientific, economic, and policy judgments simultaneously. Two, peer reviewers must be professionally qualified by training and experience to review risk assessments. Three, the findings of peer review panels should be advisory in nature. Four, members of such panels should be free from conflict of interest and should comply with existing ethical standards. And five, the results of a peer review should be documented in the form of a written report to the head of an agency, who in turn should respond in writing indicating whether that panel's advice would be accepted or not.

The fourth major issue that Congress needs to address in risk assessment legislation concerns the need to generate more data for use in risk assessment. The greatest obstacle inhibiting the scientific quality and acceptability of risk assessment lies in the paucity of abundant, high-quality data. And I think if Congress is really serious about improving the scientific quality of risk assessment, it will also address this critical issue.

How effective is H.R. 9 in improving risk assessment? I think H.R. 9 represents an ambitious attempt to codify and to restructure certain elements of the risk assessment process. It reflects a frustration that many people have had over the years concerning the

very slow pace of improving risk assessment and altering regulatory policies.

I have four specific suggestions for improving H.R. 9. First, I think it misses what perhaps may be the single greatest opportunity to improve risk assessment, which is to substantially alter the behavior of regulatory agencies who largely ignore the role of risk assessment as a principal guide for strategic planning and budgeting in the establishment of regulatory priorities.

Second, given the expanded number of risk assessments that must be prepared once this legislation is enacted, and recognizing the limitations upon Federal research budgets, regulatory agencies will be pushed to invoke data gathering authorities that exist under other statutes, many of which have never been fully utilized. As a result, agencies such as EPA will be forced to mandate expensive new testing requirements upon industry in order to supply the data necessary to conduct the voluminous number of risk assessments. I'm concerned this will make product development more expensive and will delay product approval.

Third, I believe that H.R. 9 can be improved by listening to recommendations of the National Academy of Sciences and other authoritative bodies on peer review, which is to separate risk assessment from risk management. I also think that there is no language in H.R. 9 that specifically stipulates that members of peer review panels have to be professionally qualified to review scientific evidence.

And my fourth suggestion for improving H.R. 9 is that by focusing more on the procedural aspects of risk assessment rather than on the broader strategic focus of regulation, H.R. 9 significantly increases the chance that legal and administrative issues will elbow out scientific content. If some form of citizen suit or judicial review is also upheld, I think scientists will over time be inhibited from serving on peer panels, and I think the risk assessment process itself would be more expensive and inefficient. But perhaps the greatest concern is that risk assessment could become the new battleground for competitors waging war on each other's products, and also could constitute nontariff trade barriers. And I think H.R. 9 already moves down this slippery slope to some degree, because it contains language that exempts certain product categories from review. And I would be very reluctant to see risk assessment be used to try to pick winners and losers in the marketplace.

So let me summarize by saying that I think there are elements where peer review has been expanded so that it constitutes a bureaucracy. I do think there are many now mandated testing programs that could be inflicted upon American business. I'm also concerned about new ground rules being set that will impede products entering the marketplace and expanding the number of procedural requirements that ultimately business will have to comply with. But I also believe that there is ample time and opportunity to resolve these concerns.

Other Members of the Majority party have already introduced risk legislation in other committees. I think comments from Representative Zimmer this morning contain a number of ideas for workable legislation. And so I would end where I started, I think

the opportunity to enact scientifically sound, yet workable, risk assessment legislation should not be missed. It should be seized.

Thank you for the opportunity to state my views.

[The prepared statement of Mr. Yosie follows:]

**Comments on Title III of H.R. 9**

**"Risk Assessment & Cost/Benefit Analysis For  
New Regulations"**

**of the**

**Job Creation & Wage Enhancement Act of 1995**

**Statement of  
Terry F. Yosie  
Senior Vice-President  
E. Bruce Harrison Company**

**Before the  
Committee on Science  
U.S. House of Representatives  
February 3, 1995**

Good day Mr. Chairman. My name is Terry F. Yosie, and I am Senior Vice President of the E. Bruce Harrison Company, an environmental consulting firm headquartered here in the nation's capital. My prior professional experience has included service as Vice President for Health and Environment of the American Petroleum Institute and as Director of EPA's Science Advisory Board, the principal independent peer review body advising the Environmental Protection Agency. The views I am presenting today are exclusively my own.

Thank you for the opportunity to present my views on Title III of H.R. 9, the "Risk Assessment and Cost/Benefit Analysis for New Regulations" section of the "Job Creation and Wage Enhancement Act of 1995." The proposed legislation raises a number of issues concerning ways to improve decision making to protect public health, safety and environmental quality.

As a participant in and an observer of the risk assessment process for the past 17 years, I have personally concluded that the opportunity to enact workable risk assessment legislation has never been better and should be seized. In designing workable legislation, at least two major questions should be addressed. These include:

- What are the key issues that risk legislation needs to address?
- How good a job does H.R. 9 do in improving risk assessment and regulatory decision making?

The balance of my testimony will address each of these issues.

#### **I. Key Issues Requiring a Legislative Solution**

I believe that legislation should attempt to solve four basic issues that have hampered a more effective use of risk assessment during the past two decades. These problems have been well documented by a variety of prestigious bodies, including this Committee. These issues include:

- **Applying risk assessment as a strategic planning tool in regulatory agencies to ensure that health, safety and environmental priorities are more appropriately chosen commensurate with society's understanding of real and potential risks.**

The real added value of risk assessment will lie not only in evaluating information associated with individual compounds or technologies, but as the framework for day-to-day decision making that is linked to budgetary and planning processes. When risk assessment is used in this fashion, Congress and the public at large will be in a better position to evaluate the effectiveness of environmental programs. Each new appropriation cycle will thus provide both the legislative and executive branches the opportunity to compare the seriousness of various risks, evaluate the performance of various programs designed to reduce risks, and make any necessary adjustments in authorizing or appropriating legislation.

A major objective of risk legislation should, therefore, be the incorporation of risk assessment in strategic and budgetary planning that is linked to an annual reporting system so that the public can evaluate how the risk assessment process is being managed and how effectively risks are being reduced.

- **Ensuring that high quality risk assessment data is more expeditiously and completely used in risk assessment.**

A major part of the current debate relates to the concern that regulatory agencies have been too slow in substituting scientific data in lieu of certain assumptions and models. There are several aspects of this debate that deserve mention. First, many agencies have unclearly or inconsistently applied procedures for determining when to substitute new data for assumptions and models. Strengthening these procedures would improve quality control of data collection and analysis. Second, there have been a number of instances where regulatory agencies have been too slow in reflecting the most recent scientific information in risk assessments. This is not an issue that applies to agencies alone, for the scientific community itself prefers that repeated experiments confirm the results of specific scientific findings before they are applied in decision making. Third, in a large number of instances, the delays in applying new data to regulatory policy decisions have delayed the imposition of costlier controls. EPA, for example, has continuously violated the Clean Air Act by failing to promulgate a revised National Ambient Air Quality Standard for Ozone and is now under court order to do so. Data published since the last revision of the standard in 1979 concludes that the current standard insufficiently protects public health. By neglecting to apply the most recent scientific data to standard setting over the past decade, EPA has delayed the imposition of very costly regulatory controls. There are numerous other examples of this phenomenon. Scientific data and risk assessment constitute a double edged sword--they will not conform exclusively to a regulatory or a de-regulatory agenda.

I believe that Congress should enable peer review panels to advise when new scientific information is of sufficient quality and relevance to use in policy making. As to whether such information supports a more restrictive or less restrictive regulatory policy, my own philosophy is to let the chips fall where they may.

- **Improving the peer review process**

Meeting acceptable scientific standards in developing and applying risk assessment is an on-going challenge. Over the past decade, great progress has occurred in meeting this challenge through the preparation of risk assessment guidelines, expansion of the peer review process, and the increased participation of scientists inside and outside of regulatory agencies in the risk assessment process. However, the job of improving the scientific quality of risk assessments is by no means finished.

One of the principal mechanisms to achieve this objective is through peer review. In crafting legislation to enhance the effectiveness of the peer review process, Congress should be guided by the following principles:

- 1. Peer review should focus on the scientific basis of decision making and not attempt to intermingle scientific, economic and policy judgments simultaneously.** From my experience as Director of EPA's Science Advisory Board, the quality of the peer review of any individual risk assessment was better maintained if it focused on scientific issues. In addition, the integrity of the peer review process is better preserved if decision makers can be assured that scientists are speaking on the basis of their professional expertise rather than their political judgments or their views on specific policy issues.
- 2. Peer reviewers must be professionally qualified by training and experience to review agency risk assessments.** It is possible to represent stakeholders such as industry, environmental groups, and state and local officials on such panels, but individuals from these entities should be professionally qualified. If this does not occur, public confidence in the authority and credibility of the peer review process will deteriorate.
- 3. The findings of peer review panels should be advisory in nature.** An advisory peer review process maintains the accountability for environmental policy making where it truly belongs--with the nation's elected and appointed officials. If peer review is not advisory, a new, less accountable decision making body will be established, one that would have substantial influence upon setting specific policies and determining which products enter the marketplace.
- 4. Members of such panels should be free from conflict of interest and should comply with existing ethical standards that apply to special government employees.** For example, they should be required to disclose their financial interests while serving on a peer committee. No member should review the scientific evidence pertaining to a specific product made by his/her employer.
- 5. The results of a peer review should be documented in the form of a written report to the head of an agency.** The results of a peer review should be documented in the form of a written report to the head of an agency. Such reports should be publicly available and be included as part of the public record of a regulatory proceeding. Agency heads should respond in writing to the peer review committee indicating whether its scientific advice will be accepted and, if not, offering a suitable explanation.

Congressional action on the peer review process should reflect these principles.

- **Generating more data for use in risk assessment.**

The greatest obstacle inhibiting the scientific quality and acceptability of risk assessment lies in the paucity of abundant, high quality data. As a result, regulatory agencies, the private sector, public interest groups, and the scientific community keep messaging old data, a process that exhausts both themselves and the data. The absence of good data can fundamentally distort public policy. For example, the National Ambient Air Quality Standard for Particulate Matter, one of the most important and expensive air pollution standards, relies upon a 40 year old data base for much of its scientific support. This data base was collected at a time when people burned coal to heat their homes and when the very composition of particulate matter bears little resemblance to current atmospheric conditions. The need for continuing reliance upon such a data base is a national scandal, and there are many more such scandals.

If Congress is serious about improving the scientific quality of risk assessment, it will also address this critical issue. At a time of growing concern over federal spending, however, it is unrealistic to expect that the federal government alone will provide all the necessary research support. I propose that Congress encourage scientific partnerships between government, industry and the non-profit sector to leverage their resources in support of high priority, risk-based research. Such encouragement can greatly expand the amount of high quality data available for risk assessment.

## **II. Effectiveness of H.R. 9 in Improving Risk Assessment**

H.R. 9 represents an ambitious attempt to codify and restructure certain aspects of the risk assessment process. It reflects a frustration that many people have concerning the slow pace of improving risk assessment and altering regulatory policies. If enacted in its present form, however, it would not substantially change the way risk assessment is currently practiced. Rather, it would make the current risk assessment process even more inefficient and expensive to manage. And it would generate a number of major second-order consequences upon industries subject to health, safety and environmental regulation.

My evaluation of H.R. 9 consists of two parts: 1) reviewing how well it addresses the four key problems discussed above, and 2) identifying some areas where some unwelcome, unanticipated consequences may result if the bill is enacted in its current form. Specific comments in these areas include:

1. H.R. 9 misses a great opportunity to substantially alter the behavior of regulatory agencies by largely ignoring the role of risk assessment as a principal guide for strategic planning and budgeting and the establishment of regulatory priorities. The current bill acknowledges in a limited, but essentially meaningless way the need for comparative risk

assessment, but by ignoring the opportunity to link risk assessment to the priority-setting and budgeting process, H.R. 9 omits a major option for reforming the risk assessment process.

2. H.R. 9 recognizes the importance of favoring scientific data over the use of assumptions and models in preparing risk assessments but provides no answer to the question of how additional data will be acquired. Given the expanded number of risk assessments that must be prepared once this legislation is enacted, and recognizing the limitation upon federal research budgets, regulatory agencies will be pushed to invoke data gathering authorities that exist under other statutes, many of which have never been fully utilized. As a result, agencies such as EPA will be forced to mandate expensive new testing requirements upon industry in order to supply the data necessary to conduct a voluminous number of new risk assessments. Such mandates, contained within the authorities of the Clean Air Act and the Toxic Substances Control Act, for example, will make product development more expensive and will delay product approval.

3. The peer review recommendations contained in H.R. 9 violate one of the cardinal principles of peer review as recommended by the National Academy of Sciences and many other authoritative bodies--the separation of risk assessment from risk management. By placing scientific review, economic assessment and policy analysis into the peer review function, the likelihood that such peer panels will recommend expanded controls on some industrial sources rises dramatically. In addition, there is no language in H.R. 9 that stipulates that members of such panels should be professionally qualified to review scientific evidence. Rather, peer reviewers would be selected on the basis of which constituencies they represent. This is a significant shortcoming in a bill that is intended to improve the scientific quality of risk assessments. This shortcoming increases the chance that appointments will be made on the basis of political factors or advocacy views.

4. By focusing upon the procedural aspects of risk assessment rather than addressing how the results of risk assessment can add value to the policy making process, H.R. 9 significantly increases the chance that legal and administrative issues will elbow out issues of scientific content. If some form of citizen suit or judicial review is also included, scientists will be inhibited from serving on peer panels, the risk assessment process will become even more expensive and inefficient, and risk assessment will become the new battleground for waging war on a competitor's products or imposing non-tariff trade barriers in international commerce. H.R. 9 already moves down this slippery slope by exempting certain product categories from review. Risk assessment requirements should not be used to pick winners and losers in the marketplace.

Mr. Chairman, the American people expect that when regulations are developed, they should be based upon sound science, target high priority health, safety and environmental concerns and reduce the role of government.. H.R. 9 fails to meet this expectation. Through the creation of an unaccountable peer review bureaucracy, through the expansion of mandated testing programs upon American businesses, by setting new

ground rules for how products will enter the marketplace and by expanding the number of procedural requirements that businesses will ultimately have to comply with, H.R. 9 expands the intrusiveness of government into the marketplace and, by placing so many new, burdensome and expensive requirements on the development and use of risk assessment, it eventually will reduce the importance of risk assessment in the making of regulatory policy because it will become such an unwieldy and ineffective technique.

Furthermore, by focusing primarily upon the procedural aspects of risk assessment rather than the use of risk assessment to improve the results of decision making, H.R. 9, in its current draft, constructs a Maginot Line of requirements that creative agencies and interest groups will, after the expenditure of enormous energy and resources, find ways to circumvent.

There remains ample time and opportunity to resolve these concerns. Other members of the majority party have already introduced risk assessment legislation that goes a long way towards resolving many of the issues I've discussed today. I would particularly mention H.R. 690 as introduced by Representative Zimmer of New Jersey as an example of workable legislation that addresses the high priority issues that Congress should address.

The opportunity to enact scientifically sound, yet workable risk assessment legislation should not be missed. Thank you for the opportunity to present my views.

The CHAIRMAN. Thank you very much.

Dr. Ritter.

Mr. RITTER. Thank you, Mr. Chairman. And I do want to thank my friend from Lehigh Valley, Mr. McHale, for his kind introduction. But I must say that if I was as smart as my resume sounds, I would be chairman, not of this committee, but of another one. I would still be here.

I also want to commend this committee. This is an historic day, it's an historic process, but let's face it, this committee started this process with the Chairman and with the former Chairman 15 years ago, in 1979, when no one else would even dare hold a risk assessment hearing.

Mr. Chairman, in so many ways, the capacity of science to influence the public debate has—has been limited over the years. And we have had a very difficult time separating politics from science. We've regulated to the tune of tens of hundreds of billions of dollars in costs when the science was scant and even flimsy. The system as presently constituted can't set priorities. Title III will help. Congressman Zimmer's risk ranking and priority setting legislation, H.R. 690, will help.

We've had a tough time knowing how much regulation was enough. We made great gains cleaning up our air, our water, and our land. All the American people can take justifiable pride in what we've achieved. But, Mr. Chairman, and my friends on this committee, let's face it, we have wasted a vast amount of resources chasing down infinitesimally small amounts of high profile, media-sensitive substances. These are resources that might have been used more effectively to boost jobs and American competitiveness, or really could have been applied to other environmental problems and opportunities.

A crucial question for this committee, and I really speak not as a former scientist but as someone who spent 14 years in this House and on this committee, a crucial question has to be what is the quality, indeed, what is the integrity of the science underlying the risk judgments in our regulatory efforts. Title III will help do that.

The question needs to be asked, particularly in the area of environmental regulation because it's had more than its fair share of highly charged rushes to judgment, emotionally driven decisions and political, or should we say, politicized science.

Mr. Chairman, to many, the present regulatory system is broken. That's why we are here; that's why we have this legislation. We've had things like Delaney clause, Alar, EDB. Where was the good science behind those decisions? Where was the 10-year, \$500 million, taxpayer-funded acid rain study, initiated by Jimmy Carter and Patrick—Senator Moynihan, when we reauthorized the Clean Air Act in 1990? What was the science base? What was the science base of this reauthorization that's estimated to cost up to \$50 billion a year?

Do you realize that in the Clean Air Act we are not allowed to take cost implications into consideration? And risk issues are all retrospective in the Clean Air Act. That is after a certain number of years, let's see whether the risks and benefits and costs, what they were like, everything is retrospective.

What's the scientific logic behind the asbestos program that cost America's public schools \$10 million, especially in light of other serious problems which confront these institutions? I heard Barbara Wheeler from the National School Boards Association testify. She was testifying the other day at Energy and Commerce. She talked about kids are being shot in our schools. What happened at Times Beach and are the dioxin and chlorine regulations—somebody was talking about the cluster rule for the paper industry costing tens of billions of dollars totally. Are they based on sound science?

I think it's wise and healthy to get the lead out of the air. It's a good decision. But was it wise and healthy to try to get the EPA to try to get the lead out of Smuggler's Mountain?

So let's face it, we are here because there's a lack of trust in the present regulatory process because a lot of people think it's bone broken. And that process goes beyond EPA or other agencies. It goes directly to the major statutes, and other people have mentioned this. This is a command and control statutory environment in a total quality era. If this economy behaved, as does the system which is given to EPA, the command and control system, it would be the Soviet Union. And a lot of people in EPA understand that.

You know, we have right now a law, went into effect in 1970. It's the National Environmental Policy Act, NEPA. They balanced costs and benefits of proposed actions. EPA was written out of NEPA. It was not required to balance its actions against the benefits as the act assumed. Applying risk assessment to EPA, via Title III, requires the Agency to do something similar to what the rest of the government has been doing for 20 years under NEPA.

Mr. Chairman, just a few things. Our institute has done some focusing on this issue of science and risk evaluation. Terry Yosie is a very active player in this sector of reinvention of EPA. One of the things that we've come up with is this idea of comparative risk assessment being a very important element in making these kinds of decisions. You have capability that EPA as a mentor has extended to 32 States. You have places like Columbus, Ohio, who are doing these wonderful things today with Ohio State. A Democrat, Ben Nelson, the Governor of Nebraska, is doing this with major success in Nebraska. There's some real possibilities for opening up the system, democratizing the system and bringing the States into it and bringing local governments into it that's not really in the legislation at this time, but I think there's some great opportunity there.

And in conclusion, once again, the real problem is this whole issue exists within the realm of command and control statutes, which need, to some extent, reauthorization. If they are not reauthorized in an incremental sense, there is some reason to look at an overarching unified or organic statute as it is called, where some of these changes can be made. Make risk assessment and some of the kinds of things you want to do in Title III really happen.

Thank you very much, Mr. Chairman.

[The prepared statement of Mr. Ritter follows:]

# N E P I

National Environmental Policy Institute

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Testimony

on behalf of

National Environmental Policy Institute

on

**Title III, Contract with America,  
Risk Assessment and Cost/Benefit Analysis for New Regulations**

before the

Science Committee  
United States House of Representatives  
2318 Rayburn House Office Building  
Washington, D.C.

February 3, 1995

by

The Honorable Don Ritter  
Chairman  
National Environmental Policy Institute

## INTRODUCTION

Mr. Chairman, I want to thank you for the opportunity to testify on Title III of HR 9, *Risk Assessment and Cost/Benefit Analysis for New Regulations*. As a former member who sat on this committee, who first authored risk bills in Congress starting in 1979, and who was exposed to some of the slings and arrows of risk assessment over the years, I don't need to tell you what a pleasure and a privilege it is to be back before you, and your esteemed colleagues today. Congratulations to you all.

Specifically, the Contract for America has elevated the discussion of risk assessment to the highest levels of policy seeking to put technological hazards in a more rational perspective. Thus, the Contract has performed a significant service to the American people.

It is important that we all comprehend the context of this issue which is presently receiving the ultimate in attention from one of the Congress' great committees. This bill is the first to be taken up by this committee in the historic 104th Congress. And this committee now stands at the junction between the works of the America's science community, the most respected in the world, -- and regulatory policy formulated by government agencies to make American industry, the strongest in the world, -- healthier, safer and less harmful to the environment.

Mr. Chairman and distinguished members of the Committee, your work is so important, because in many ways our best science has yet to have the opportunity to provide the American people with the most intelligent and well-reasoned regulation. We have had a difficult time separating politics from science. We have regulated to the tune of tens of billions of dollars in excess costs when the science was scant, even flimsy.

We have had a tough time knowing how much regulation was enough. We have made great gains in cleaning up our air, our water and our land. All Americans can justifiably take pride in what we have achieved. However, we have also wasted a vast amount of resources chasing down infinitesimally small amounts of high profile media-sensitive substances; resources that might have been used more effectively to boost jobs and American competitiveness at home and abroad, or could have been applied to other environmental problems and opportunities.

Title III of HR 9 has the potential to help decision-makers and regulators know better where to put our energies, our talents and our dollars. Risk assessment that is open, transparent, rigorously peer reviewed, democratized and demystified can go a long way to changing a broken system.

Mr. Chairman, risk and cost/benefit analyses are essential tools that can help both Congress and federal agencies make good, cost effective decisions which protect health and the environment. These tools are also essential for the American public to better understand environmental issues, how they can be most effectively addressed and at what cost, both to

individual citizens and to the country as a whole.

## THE INSTITUTE'S WORK

Before I address the legislation, I would like to talk about the National Environmental Policy Institute in general and its Reinventing EPA and How Clean is Clean? initiatives in particular.

The National Environmental Policy Institute (NEPI) is a non-profit, bipartisan organization of environmental leaders who seek to advance new consensus ideas for developing big-picture environmental policies based on sound science, risk assessment, economic analysis, and to involve new constituencies with the capacity to influence environmental debate.

NEPI is dedicated to establishing positive environmental priorities and re-focusing the environmental debate to ensure that the highest priorities receive appropriate attention. In the process, NEPI reaches out to raise the awareness of important constituencies including members of Congress, senior officials in the Executive Branch, the media and the public.

NEPI is independent of government and industry, but works closely with both to promote effective environmental policies. It draws upon the collective skill, experience and knowledge of elected officials, industry representatives, government policy makers, academics and members of the environmental advocacy community.

Mr. Chairman, our *Reinventing EPA* Working Group, some one hundred and fifty persons strong, is diverse and bipartisan. We formed this Working Group to develop more effective policy options for an EPA of the '90's and beyond and to provide the intellectual and substantive base for more effective environmental management and reform. We seek change through administrative, regulatory or statutory changes, whichever does the job.

The Working Group is chaired by author and environmental policy innovator Bruce Piasecki, Ph. D., of Rensselaer Polytechnic Institute. The Working Group Director is F. Scott Bush, former environmental policy analyst at EPA and the Center for Strategic and International Studies.

### *Individual Sectors of Reinvention*

At the Working Group's inaugural meeting in October, 1994, the following focus areas were selected as initial sectors of reinvention:

#### **National/Agency Objectives and Priorities**

**Chair:** Charlie Grizzle, President, The Grizzle Company and former Assistant Administrator for Administration and Resources Management, EPA

### **Rethinking the Role of Science and Risk Evaluation**

**Co-Chair:** Don Elliott, Partner, Fried, Frank, Harris, Shriver & Jacobson and former General Counsel, EPA

**Co-Chair:** Dr. John Moore, President, Institute for Evaluating Health Risks and former Assistant Administrator of Pesticides and Toxic Substances at EPA.

### **Non-Mandatory Pollution Reduction: Moving Beyond Command and Control**

**Chair:** Darryl Banks, Director, Technology & Environment, World Resources Institute

### **Intergovernmental Change - Federal, State and Local**

**Chair:** Ned Sullivan, Deputy Commissioner, New York State Department of Environmental Conservation.

We are in the process of launching three new sectors: Alternative Environmental Benefits, Unified/Organic Environmental Statute and Compliance/Enforcement in an Era of Reinvention. Tom Zosel, Manager of Pollution Prevention at the 3M Corporation, and Fred Ellerbusch, Director of Corporate Environmental Affairs at Rhone-Poulenc, have agreed to co-chair the sector examining a Unified/Organic Statute. Roger Marzulla, Partner at Aiken-Gump and former Assistant AG of DOJ's Land and National Resources Division, and Ted Garrett, head of the Environmental Practice at Covington and Burling, have agreed to co-chair the sector on Compliance/Enforcement. Joyce Kelley, President of Wildlife Habitat Council, and Bill Chandler, Director of Conservation Policy at the National Parks and Conservation Policy, have agreed to co-chair the sector on Alternative Environmental Benefits.

I would like to devote the first part of my testimony to the work of the Institute in the science and risk area and how it relates to the subject of today's hearing. I would like to make some recommendations to the Committee in the risk area, and then comment on the cost/benefit aspects of the legislation before you. I will address my comments to the environmental policy implications of the Bill, as that is where the expertise of the Institute lies.

### ***The Science Sector***

Our sector on "Rethinking the Role of Science and Risk Evaluation", in the *Reinventing EPA* initiative has been meeting to discuss new ways to ensure that good science is used effectively by policy makers, both in Congress and the Administration, to make wise, cost effective decisions on health and the environment. It is chaired by a recognized expert in the field, Don Elliott, the Julien and Cornell Professor of Environmental Law at Yale, a former General Counsel at EPA, and currently head of the Environmental Section at the law firm of Fried, Frank, Harris, Shriver and Jacobson. The sector involves a cross section of some 25 experts in the risk field, and is co-chaired by Dr. John Moore, former Assistant

Administrator for Pesticides and Toxic substances at the EPA and currently President of the Institute for Evaluating Health Risks (IEHR). The Sector is currently focusing on five areas:

1. **The role of scientific research and risk assessment in developing environmental goals;**
2. **Creating an effective institutional structure for science and risk assessment in developing and implementing policy;**
3. **Comparative risk ranking;**
4. **Improving risk communication; and**
5. **The role of science and risk assessment in industrial innovation and trade, national and international.**

We are focusing on the reliability risk assessment process and how it can help Congress and Agencies make good environmental decisions. The key features of this are integrity of the risk assessment process and the science employed in that process. The word integrity should be emphasized. Now, Mr. Chairman, before I comment directly on Title III of the Contract with America, allow me to briefly relate to you some of the initial conclusions reached by this sector. This can help ensure that Title III gives the nation a more effective, less costly and less intrusive environmental policy -- a policy which strengthens the economic position of the United States at home and in a strongly competitive world economy.

## **INITIAL CONCLUSIONS FROM OUR STUDY**

The sector on *Rethinking the Role of Science and Risk Evaluation* has identified five significant areas of impact.

### **1. The role of scientific research and risk assessment in developing environmental goals**

Science should be used to both inform the public and help frame the policy debate. It can tell us what we know, and often just as important, what we don't know. All too often, science and the role of scientists are marginalized and do not fully factor into the policy process. Currently, neither Congress nor the agencies make effective use of science and scientists to help them make decisions in the early stages of the legislative or policy process, and all too often, attempt to use science inappropriately to justify decisions already made on policy or political grounds. We don't use science effectively to help prioritize our environmental problems or determine the most cost effective measures to address these problems. Thus, science is all too often abused and environmental policy is ill-served.

Moreover, statutory deadlines often prevent adequate insertion of science into the process.

Risk assessment is not purely a scientific process, but contains many policy choices and assumptions. Decisions about what to study, what models to use and how to use incomplete data reflect policy choices, not science alone. As noted in the recent Department of Energy report, *Choices in Risk Assessment*, authored by NEPI's Director of Science Policy Studies, Steve Milloy, "risk assessment can be designed and biased to achieve pre-determined regulatory outcomes and objectives." Risk assessment is a policy tool which draws upon scientific information. While the policy agenda and its integrity are critical factors, risk assessment is only as good as the scientific information upon which it was based. This means that rigorous peer review, and "consensus science" are in for a big lift if HR 9 passes.

I want to add a caveat at this time: even the best risk assessment process is no substitute for an improved regulatory process. In itself, risk assessment will not ensure that good policies are adopted. The science of risk assessment can be a critical tool for assessing priorities, but it is not sufficiently developed to provide all the answers. However, it will give us much more than what we have today.

For example, today there are no generally accepted risk assessment techniques that relate to ecological risks. We can make decisions in monetary terms, but there is no consensus on the method of pricing, and just where do ecological risk assessments begin and end?

## **2. Creating an effective institutional structure for science and risk assessment in developing and implementing policy**

As our economy becomes more global in scope, we need to recognize that decision makers and the public must compare and balance risks when confronted with often difficult policy choices. One conclusion, reached by an early consensus, is that the risk assessment process should be transparent and peer-reviewed so that Congress, policy makers in agencies, and the public can easily understand the risks we are protecting against. All too often the entire risk assessment process is, to quote Winston Churchill "It is a riddle, wrapped in a mystery, inside an enigma."

Indeed, the initial conclusions of our sector support many of the elements of Title III. For example the sector members believe that conservative default assumptions (in the absence of relevant available information) should be made explicit, scientific uncertainties should be reflected through a range of risk estimates, realistic exposure data should be used; and where estimates are used, the basis on which they are chosen should be made public.

Transparency is essential for another reason: to ensure the credibility of the process which is significant for obtaining public trust in agency actions. Speaking of trust, I would add that we now have the potential for attaining a truly bipartisan environmental policy, one

that has been absent for a long time, one that NEPI is committed to achieving. To this end, it is essential that all key participants be involved early in the risk assessment process, and that they are not relegated to the position of simply commenting on what agencies have already decided upon. I suggest that the legislation be strengthened to make clear the importance of early involvement of stakeholders in the process.

State governments have rapidly expanded their capability to perform risk assessments and are currently undertaking them on a wide scale. We believe that state governments have much to offer and should be heavily involved in the entire process of implementing this legislation, when adopted. State agencies should participate with federal agencies in developing risk assessment processes. In addition, many local governments now have the capacity to participate at a high level in the debate--witness Columbus, Ohio and its relationship with a risk assessment advisory group centered at Ohio State University.

From my point of view, one way to accomplish this goal of greater integration is to establish a federal/state/local body to give input to the various federal agencies as they attempt to implement this legislation. There is another important reason for such an approach: We must ensure that the risk assessment program envisioned in this legislation is not so restrictive that we end up regulating how risk assessment is done. Allow me to quote our sector Chair, Don Elliott, who served on the Carnegie Commission's Science, Technology and Government Task Force and testified before the House Science, Space, and Technology Subcommittee in 1993:

"Agency missions are often guided by disparate, statutory mandates and cultures. These characteristics may be difficult to reconcile in one centralized risk assessment body. Risk-based agenda setting should not be performed in a vacuum, however. Agencies should share and compare risk data and should coordinate efforts to achieve consistency where possible."

This also applies to states and potentially to localities.

Effective internal and external peer reviews are essential ingredients to any risk assessment process. It is essential to encourage open communication between a broad spectrum of interested parties and stakeholders. The process should both inform the participants and be receptive to challenges to risk assessment assumptions and alternative data and judgments.

I would make another recommendation on the legislation: It is very important that when there are disagreements, they be discussed prominently in the final risk assessment report, and not buried as is all too often the case today. And where the particular agency disagrees with alternative assessments recommended by the peer review process, the legislation is silent about what happens. I suggest that agencies be required to give explicit reasons on how and why they differ from peer review recommendations. Again, such reasoning should be prominently displayed in the report.

### 3. Comparative Risk Ranking Process

Risk assessments can also help us compare and prioritize risks, both at the national and state/local level. Michigan has recently completed such a project and many others are currently underway, many of which the EPA sponsored. Well prepared risk assessments are essential elements in any comparative risk process. They can help Congress assess the need for new legislation or conversely when reauthorizing existing legislation. They can help states and localities in comparing their own risks to better utilize their limited resources. And they can also help agencies, such as the EPA, to reassess their own priorities and how they can best spend their limited funding. Having been in a big brother relationship for so long, the time has come for EPA to learn from states and local governments as well.

### 4. Improving risk communication

The American public is getting increasingly put off by the "scare of the month" approach to addressing environmental and natural resource issues. People are confused; they are angry; they think that government officials are a bunch of keystone cops. Relative to other human health concerns, much of the current contentiousness in environmental policy is the result of inaccurate, and often irresponsible, reporting by the media. An open and inclusive risk assessment process would go a long way to help the media better understand the scientific and policy issues involved in dealing with environmental problems, so that the public may have a better understanding of the real extent of potential threats. Fear mongering is big business. HR 9 will help mitigate it.

Various EPA reports have shown that there is a great disparity between expert and public perceptions of risk. However, there are currently various initiatives taken at the state and local levels which suggest that the differences between experts and the public are not necessarily irreconcilable, and in fact can be harmonized through the exchange of information. This is good news. People will respond to intelligent information. Good risk assessments are an essential part of this process as they make clear all assumptions (both scientific and policy) upon which decisions are made; and therefore, provide information to enable states, cities and citizens to make their own judgements on which priorities are most important. EPA's Comparative Risk Assessment efforts with the states deserve a lot of credit.

### 5. The role of science and risk assessment in industrial innovation and trade.

As our economy becomes more global, we must ensure that our environmental policies support and complement the changes that take place in our economy. We must be careful not to add unnecessary burdens on our industry, especially in the development of new products and processes. Good science and risk assessment processes play a significant role in how American industry determines future investments needed for our economy to grow. All too often, industry is viewed by some agency regulators as an adversary which doesn't

share the same environmental goals as the rest of the society. We should look for opportunities where industry and government can work cooperatively for the greater common good.

Our Reinventing EPA initiative will be continuing at least for another year, and we have only begun to address the major policy and practical implementation issues which are integral parts of a reinvented and reinvigorated national environmental policy.

## INTEGRITY OF SCIENCE IN THE PROCESS

A crucial question for this committee has to be: What is the quality, indeed, what is the integrity of the science underlying the risk judgments in our regulatory efforts? This question must be asked, particularly in the area of environmental regulation because it has had more than its share of highly charged rushes to judgment, emotionally driven decisions, and political or should we say politicized science.

We have made great gains, but let's not kid ourselves, we've had more than a few bad experiences. One really has to question where the good science was in the Delaney clause, Alar and EDB decisions? Where was the ten year, \$500 million, taxpayer funded "Acid Rain" study initiated by Jimmy Carter and Patrick Moynihan when we reauthorized the Clean Air Act in 1990? What was the science-base of this reauthorization that's estimated to cost \$50 billion per year?

What is the scientific logic behind the Asbestos Program that has cost America's public school's \$10 billion, especially in light of the other serious problems which confront these institutions? As Barbara Wheeler, member of the National School Boards Association, stated, before two subcommittees of the Energy and Commerce Committee on Wednesday, February 1, 1995 "kids are being shot in our schools." Are the dioxin and chlorine regulations, costing tens of billions of dollars, based on sound science? I think it was wise and healthy to get the lead out of the air, but was it wise to try and get the lead out of Smuggler's Mountain in Aspen?

To paraphrase a famous battery commercial, I could "go on . . . and on . . . and on. . . and on." The result is this Mr. Chairman, risk assessment is only as good as the science that goes into it. Maintaining the integrity of science in this process is important to everyone: federal, state and local agencies, legislative bodies, business, and the American people. This poses quite a challenge to the Science Committee.

## CONCLUSION

I would like to draw on Senator Moynihan's distinction between the techniques of risk assessment and how that information is used to make policy decisions or what he calls "risk management" decisions. Congress has been asking the wrong question with respect to risk assessment. It has been asking "what level is safe?" Due to uncertainties inherent in

science, risk assessment can not provide the answer to that question. No amount of scientific information can answer that question. However, risk assessment, if utilized properly, can be a useful tool for obtaining general information about risks. A more useful question, and the question Congress should be asking, is "how much are we willing to pay to reduce risk to level X or to level Y, understanding that we have these uncertainties?" I think that's a simple way to pose the problem which the legislation before you is intended to address. If we keep this in mind, it will go a long way to keep it simple.

Some, but not all, in the environmental community may be nervous about change and view this bill and the risk assessment process as a way to make it more difficult for EPA to do its job. Actually, this bill should help EPA carry out its mission as it will help improve the effectiveness of environmental policy by focusing resources in a way that most efficiently reduces human health risk.

Members of the Committee, every agency in the government engages in a process similar to that under the National Environmental Policy Act of 1970 (NEPA), where they balance the costs and benefits of proposed actions. The EPA was "written out" of NEPA: it was not required to balance its actions against benefits, as the Act contemplated. Applying risk assessment to EPA through Title III, only requires the agency to do something similar to what the rest of the government has been doing for 20 years under NEPA. It is not a way to eliminate environmental regulations, but a way to improve them and to help focus agency efforts on realistic objectives that have the greatest benefits.

Finally, I would like to make some personal observations and recommendations to you, my former colleagues, in many cases good friends, and to the recent members.

Please, do not misinterpret what I am about to say: Important as this legislation is, it is only a first step on a long road to a more rational, more beneficial and less costly environmental policy for the nation. By itself, it won't change the way agencies do business, unless you, the members of Congress, the Administration, the agencies affected, industry, the environmental community, and most importantly, the citizens, make it work. For this Committee, this means oversight, oversight and more oversight, at least at the beginning.

One immediate problem that will limit the potential of this legislation: the linkage between risk assessment and the generic statutes under which EPA and other agencies operate. I'm sure that you are well aware of the many instances in which these statutes actually restrict or preclude the EPA from using even the best risk analyses to affect the way it operates. I think it is important for Congress to be aware of such potential "disconnects" when reauthorizing statutes, and as part of its oversight responsibilities.

These statutes, by and large, reflect the command and control regulatory system which has evolved over the years and are too often inflexible, anti-innovation, punitive and too costly. Basically, risk assessment alone cannot cure the faults of such a large system.

For that, broad-based changes, such as those proposed in NEPI's *Reinventing EPA* Working Group, are necessary. For that, both the EPA and environmental policy must be reinvented. For that, Mr. Chairmen, the major statutes must be addressed. This may occur incrementally through reauthorizations, but conceivably could also take place in the form of a unified or organic statute, encompassing all of the individual statutes under a more multi-media, market-driven, less command and control aegis. The benefit, environmentally as well as economic could be enormous.

Mr. Chairman, we at NEPI stand ready to assist you and the Committee in addressing these issues in any way we can -- through an open, substantive, broad-based approach. Risk and other issues will be discussed at our upcoming February 16 event, the **Roundtable for Reinvention, Environmental Leadership in the 104th Congress**. Speaker Newt Gingrich, Administrator Carol Browner, Chairmen of the relevant House and Senate committees and subcommittees, and many others will be present.

I am available to answer any questions you might have.

The CHAIRMAN. Thank you very much.

Mr. Auchter.

Mr. AUCHTER. Thank you, Mr. Chairman, and Members of the committee. I appreciate the opportunity to be with y'all this afternoon.

My name is Thorne Auchter. I served as Assistant Secretary of Labor of the Occupational Safety and Health Administration from 1981 through 1984. I'm currently Director of the Institute for Regulatory Policy here in Washington, D.C., and my remarks here today should be attributed to me and to no other entity with which I may be involved.

I am here today to offer the committee the perspective of a former Federal regulator, as it considers Title III of H.R. 9.

First, let me say that I am a strong supporter of H.R. 9, Title III. It is absolutely necessary that Congress finally embrace the basic principle that all environmental, safety, and health regulatory decisions be based upon an understanding of the relationship between risks, costs, and benefits, and transmits that decision to the regulatory agencies.

The administrator of a Federal regulatory agency is its chief executive officer. As such, he or she is responsible for all of the Agency's decisions. But obviously that individual has neither the time nor the capacity to know everything under his or her jurisdiction. He must rely on the systems and procedures that are available to him as executive decisions are required to be made.

Let's take OSHA as an example. The Occupational Safety and Health Act says that the Agency is created to assist employers and employees in reducing injuries and illnesses in the workplace. That is its goal, its mission. Then the act goes on to describe the basic tools available to the Agency in carrying out that mission, standards promulgation and review, enforcement, training, education, State programs, and new and innovative programs in safety and health. And in executing most of those programs there are generally accepted and understood systems which define the process to be used by that agency, or any other agency.

There are agency regulations which describe the mechanisms whereby the Agency operates State plans or consultation or innovative programs. There's the field operations manual, available to the public, covering all of OSHA's enforcement policies. There are the Office of Personnel Management guidelines under statutory authority that provide the rules for personnel issues. There are the basic accounting rules used by the entire world to deal with fiscal matters. There is the Administrative Procedure Act which provides guidance to agencies for formal rulemaking, and the Federal Advisory Committee Act, for operations of advisory committees, and the Paperwork Reduction Act and the Regulatory Flexibility Act, and so on. But there are no generally accepted rules for guiding agencies in the area of estimating risk.

That is a terrible position in which place the risk manager, the individual who is ultimately responsible for executing the statutes which you create.

It has been said that risk assessment is not a panacea. Of course it's not. But it is an invaluable starting point for the consideration

of regulatory issues, provided it is systematically employed through the adoption of common principles.

Today, if two agencies did a risk assessment on the same subject, there's no guarantee that the results would agree. To the contrary, it is much more likely that the results would disagree. Moreover, if the same agency did a risk assessment twice on the same subject, the results would also most likely differ greatly. For the risk manager, that poses a terrible dilemma, ultimately forcing him to rely on an individual's or group's opinion of the issue, more than relying on the integrity of a basic system, a system provided to him by Congress, like most of the other procedures the agencies use.

Further, as a risk manager looking at an issue, I would want the most realistic estimate of the risk under discussion. And in that estimate, I would want to clearly and concisely understand the difference between fact and speculation.

Today, if the public reads there are 50,000 traffic fatalities each year, that number is real. Real individuals, real mothers and fathers and sons and daughters. But then if they turn the page and read that some study has concluded there are 10,000 excess cancer deaths each year due to exposure to some substance, they might believe that number to be equally real. That would be incorrect. That number is most probably a statistical comparison based on a series of worst-case hypotheses or guesses that is anything but real.

Regulatory agencies must not be driven by such an approach. The information base provided to Federal risk managers should be created by a relatively uniform process whose goal it is to produce realistic estimates of risk, and which clearly distinguishes between what is known and what is not known. This is a fundamental necessity which should be applied throughout the Federal environmental safety and health regulatory scheme, past, present and future. And it must be enforced through congressional oversight and through judicial review.

I know that concerns have been raised by many about judicial review. And I'm no great fan of the court system myself. However, think for a moment of the reaction inside the bureaucracy if Congress were to pass a bill requiring a process which would more consistently produce realistic estimates of risk, but then said, oh, by the way, this is not judicially enforceable, nor does it modify any existing statute. It seems to me that this would be self-defeating.

If you accept the premise that risk assessment should produce realistic estimates of risk, and should clearly distinguish between what is known and what is not known as a fundamental principle of our environmental safety and health regulatory system, then the issue becomes how to have a logical system which would allow the public to request that risk assessments be reviewed.

I suggest that the committee consider a petition process, whereby the public, based on certain criteria, could petition the Agency head to review a risk assessment for consistency with the risk assessment guidelines. If that petition were denied, the public would then have access to the court system. This is not only logical, but also necessary and appropriate.

In a letter published in the December 9th, 1994, issue of Science magazine, 18 distinguished scientists from Johns Hopkins, Yale,

Purdue, and many other universities, discussed EPA's draft dioxin reassessment. In it they stated, quote, the conclusions of EPA's current risk characterization are thus heavily dependent upon many unproved assumptions and untested hypotheses. And they go on to say, quote, we urge EPA to clearly distinguish regulatory policy from matters of scientific fact. Otherwise, the press and public will surely misinterpret the hypothetical risks presented in the reassessment as real.

Mr. Chairman and Members of the committee, it is clear from the activities here in Congress during the past two years, from the overwhelming bipartisan support in the Senate for the Johnston amendment in May, '93, to the bipartisan House vote on the EPA cabinet bill, and then to the powerful expression of congressional sentiment in support of the Walker amendment to the green technologies bill, to the testimony before numerous committees by the private sector, State and local government, scientists, academia, and former Federal officials, that there is tremendous support for this next major improvement of the Federal regulatory system. The public want it and the environmental safety and health regulatory agencies need it.

Thank you very much.

[The prepared statement of Mr. Auchter follows:]

**WRITTEN TESTIMONY OF THORNE AUCHTER  
FORMER ASSISTANT SECRETARY OF LABOR  
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION**

Committee on Science  
U.S. House of Representatives  
February 3, 1995

My name is Thorne Auchter. I served as Assistant Secretary of Labor-Occupational Safety and Health Administration from 1981-1984. I am currently Director of the Institute for Regulatory Policy here in Washington, D.C. My remarks here today should be attributed to me and to no other entity with which I may be involved. I am here today to offer the committee the perspective of a former federal regulator as it considers Title III of H.R. 9.

First, I am a strong supporter of H.R.9, Title III. It is absolutely necessary that Congress finally embrace the basic principle that all Environmental, Safety and Health regulatory decisions be based upon an understanding of the relationship between risks, costs, and benefits, and transmits that decision to the regulatory agencies.

The administrator of a federal regulatory agency is its Chief Executive Officer. As such he/she is responsible for all the Agency's decisions. But obviously that individual has neither the time nor the capacity to know everything under his/her jurisdiction. He must rely on the systems and procedures that are available to him as executive decisions are required to be made.

Let's take OSHA as an example. The Occupational Safety and Health Act says that the agency is created to assist employers and employees in reducing injuries and illnesses in the workplace. That is its goal, its mission.

Then the Act goes on to describe the basic tools available to the agency in carrying out that mission: standards promulgation and review, enforcement, training, education, state programs and new and innovative programs in safety and health.

And in executing most of those programs there are generally accepted and understood systems which define the process to be used by that agency, or any other Agency.

There are Agency regulations which describe the mechanisms whereby the Agency operates state plans or consultation, or innovative programs. There is the Field Operations Manual, available to the public, covering all of OSHA's enforcement policies. There are the Office of Personnel Management guidelines under statutory authority that provide the rules for personnel issues. There are the basic accounting rules used by the entire world to deal with fiscal matters. There is the Administrative Procedure Act which provides guidance to agencies for formal rulemaking, and the Federal Advisory Committee Act for operations of advisory committees, and the Paperwork Reduction Act, and the Regulatory Flexibility Act, and so on.

But there are no generally accepted rules for guiding agencies in the area of estimating risk. That is a terrible position in which to place the Risk Manager-the individual who is ultimately responsible for executing the statutes which you create.

It has been said that Risk Assessment is not a panacea. Of course it's not. But it is an invaluable starting point for the consideration of regulatory issues, provided it is systematically employed through the adoption of common principles. Today, if two agencies did a risk assessment on the same subject, there is no guarantee that the results would agree. To the contrary, it is much more likely that the results would disagree.

Moreover, if the same agency did a risk assessment twice on the same subject, the results would also most likely differ greatly.

For the Risk Manager that poses a terrible dilemma, ultimately forcing him to rely on an individual's or group's opinion of the issue more than relying on the integrity of a basic system-a system provided to him by Congress, like most of the other procedures the agencies use.

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But then, if they turn the page and read that some study has concluded that there are 10,000 excess cancer deaths each year due to exposure to some substance, they might believe that number to be equally real. That would be incorrect.

That number is most probably a statistical comparison based on a series of worst case hypotheses (guesses) that is anything but real.

Regulatory agencies must not be driven by such an approach.

The information base provided to federal risk managers should be created by a relatively uniform process whose goal it is to produce realistic estimates of risk and which clearly distinguishes between what is known and what is not known.

This is a fundamental necessity which should be applied throughout the federal environmental safety and health regulatory scheme-past, present and future. And it must be enforced-through congressional oversight and judicial review.

I know that concerns have been raised by some about judicial review. I am no great fan of the court system myself.

However, think for a moment of the reaction inside the bureaucracy if congress were to pass a bill requiring a process which would more consistently produce realistic estimates of risk but then said "Oh, by the way, this is not judicially enforceable, nor does it modify any existing statute".

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In a letter published in the December 9, 1994 issue of Science magazine eighteen distinguished scientists from Johns Hopkins, Yale, Purdue and many other universities discussed EPA's Draft Dioxin Reassessment. In it they stated:

The conclusions of EPA's current risk characterization are thus heavily dependent upon many unproved assumptions and untested hypotheses ...

And they go on to say :

We urge EPA to clearly distinguish regulatory policy from matters of scientific fact. Otherwise, the press and public will surely misinterpret the hypothetical risks presented in the reassessment as real".

Mr. Chairman and members of the Committee, it is clear from the activities here in Congress during the past two years, from the overwhelming bipartisan support in the Senate for the Johnston Amendment in May 1993 to the bi-partisan House vote on the EPA cabinet bill to the testimony before numerous committees by the private sector, state and local government, scientists, academia and former federal officials that there is tremendous support for this next major improvement of the federal regulatory system. The public want it and the environmental, safety and health regulatory agencies need it.

Thank you very much for the opportunity to testify today on this important issue.

The CHAIRMAN. Thank you, Mr. Auchter, and thanks to each member of the panel.

Congressman Brown.

Mr. BROWN. Thank you, Mr. Chairman.

First, since this is our concluding portion of this two-day hearing on H.R. 9, may I say to you that I think these have been amongst the most enlightening two days of hearings that I have had the pleasure of participating in for some time, and I want to pay you the full compliment for having encouraged this sort of an analysis.

Secondly, may I ask unanimous consent to insert one additional submission from—on this bill, from the Environmental Defense Fund, which came in during the course?

The CHAIRMAN. Without objection.

[The information follows:]



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**TESTIMONY OF THE ENVIRONMENTAL DEFENSE FUND  
ON TITLE III OF H.R. 9,  
RISK ASSESSMENT AND COST/BENEFIT ANALYSIS**

**before the**

**HOUSE COMMITTEE ON SCIENCE**

**FEBRUARY 3, 1995**

*National Headquarters*

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The Environmental Defense Fund, a national nonprofit environmental research and advocacy organization with over 250,000 members, appreciates this opportunity to present testimony on Title III, Risk Assessment and Cost/Benefit Analysis for New Regulations, of H.R. 9. This testimony has been prepared by Ellen Silbergeld and Karen Florini, who are respectively Senior Toxicologist and Senior Attorney with EDF's Toxics Program.<sup>1</sup>

Since its founding in 1967, EDF has believed that the nation's health, safety, and environmental policies must be based on sound science. We support use of risk assessment and cost/benefit analysis,<sup>2</sup> in appropriate instances, with a *full* recognition of the considerable limitations of those analytical tools.<sup>3</sup> It is also essential to recognize that doing such analyses properly is resource-intensive, while doing them poorly both wastes resource and yields affirmatively misleading results.

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<sup>1</sup> Dr. Silbergeld has extensive expertise in risk assessment and cost/benefit analysis, particularly in the context of Environmental Protection Agency activities. From 1983 to 1989, and then from 1994 to the present time she has been an appointed member of EPA's Science Advisory Board; she has also served on several National Academy of Sciences committees reviewing risk assessment practice. Formerly at the National Institutes of Health and now as a professor of toxicology and epidemiology at the University of Maryland Medical School, she conducts research on the mechanisms of toxicity of lead and dioxin, with particular emphasis on neuro-developmental and reproductive toxicity. Over the last twenty years she has published over 200 papers, chapters, and abstracts. She is the editor-in-chief of the international scientific journal **Environmental Research**, and a member of the editorial board of several other scientific publications. She participates in the peer review process for government agencies, private foundations, and many scientific journals around the world.

<sup>2</sup> Indeed, EDF has applied elements of this type of analysis in an examination of opportunities to prevent significant diseases in which the environment plays a role. See E.K. Silbergeld (1993), *Investing in Prevention: Opportunities to Reduce Disease and Health Care Costs Through Identifying and Reducing Environmental Contributions to Preventable Disease*. Washington, DC: Environmental Defense Fund (copy appended as Attachment 1).

<sup>3</sup> A discussion of the limitations of risk assessment and cost/benefit analysis is appended as Attachment 2).

Unfortunately, enactment of Title III in anything like its current form would be a step in the wrong direction. Because of its inflexibility and critical lack of focus, Title III's provisions would impair public health by hamstringing programs designed to protect health, safety, and the environment despite the overwhelming popularity of such programs among all voters.<sup>4</sup> Title III would also make it more difficult for agencies to incorporate scientific advances, and would encourage the use of junk science.

These deficiencies matter because careless use of risk assessment and cost/benefit analysis is a sure path to inadequate protection of health, safety, and the environment. These analytic tools can support adoption of regulations, but too often the problems of data gaps and methodologic limits can be used to excuse inaction.

Regrettably, Title III does nothing at all to address these problems and others that both pervade and go beyond risk assessment and cost/benefit analysis. Specifically, current law creates strong incentives for industry to *avoid* developing and releasing accurate information on toxicity and compliance costs, because doing so decreases the likelihood that anyone will identify a problem or require steps to fix it. Current law also fails to create incentives for the private sector to investigate and adopt ways of avoiding or reducing risks in the first place. Finally, current law provides incentives to drag out debates over uncertainties (real and imagined), rather than resolving them to act promptly on the most relevant information as it becomes available.

It is possible to create incentives that reward action rather than delay. One conspicuously successful example of this approach is found in California's Proposition 65, under which over risk assessments for 282 chemicals have

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<sup>4</sup> Among voters in the most recent election, Republicans as well as Democrats were far less likely to say that environmental programs go too far than to say they don't go far enough. The poll of 1,201 voters in the 11/8 Congressional election was conducted by Peter D. Hart Research Associates 12/1 through 12/4, and has a margin of error of +/- 3.2%.

IN GENERAL, ENVIRO LAWS:	ALL	DEM	GOP
Don't go far enough	41%	50%	34%
Strike the right balance	21	23	21
Go too far	18	10	25
Depends/Some good, some bad	15	12	16
Not sure	5	5	4

been performed and turned into enforceable standards far more quickly and with far fewer resources than is imaginable under federal law -- and not a single one of the resulting standards has been challenged in court by any affected party.<sup>5</sup> Title III, however, simply reinforces existing incentives for inaction and delay.

Those delays matter, because environmental hazards continue to cause significant amounts of preventable illness and premature death in the U.S. population. Although some commentators have suggested that the numbers of premature deaths caused by toxic substances are too small to warrant societal concern, even conservative (i.e., low) estimates indicate that **the annual number of premature deaths from toxic substances in the U.S. exceeds the combined total from handgun homicides and sexually-transmitted AIDS**<sup>6</sup> -- two issues of critical concern to the public and policymakers. The notion that our society need make no further investments in environmental protection is simply not supported by the available data. And legislation that would imperil the implementation of programs designed to safeguard public health -- as Title III would do -- is likewise insupportable.

Key problems in Title III can be summarized as follows:

- \* Title III fails to strategically invest scientific and government resources, instead taking a broad-brush approach that potentially encompasses hundreds or thousands of agency activities. The bill mandates that agencies engage in resource-intensive preparation of formal cost-benefit analyses and risk assessments, **and** conduct peer review of all information used in them, for all so-called major rules. The \$25 million threshold for defining a major rule is 0.0004% of the U.S. Gross Domestic Product; it is also one-quarter of the \$100 million cutoff used by Presidents Reagan, Bush, and Clinton.<sup>7</sup> What's more, the three-part

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<sup>5</sup> See "California's Prop. 65: Lessons for the National Risk Debate?," Risk Policy Report, Jan. 20, 1995, pp. 40-41 (copy appended as Attachment 3).

<sup>6</sup> McGinnis and Foege (1993). Actual Causes of Death in the United States. Journal of the American Medical Association, Vol. 270, pp. 2207-2212. (Copy appended as Attachment 4.)

<sup>7</sup> Although section 3301(h) substitutes \$100 million for \$25 million in the definition of major rule, this higher threshold is mooted out by the requirements in section 3301(b). The latter requires peer review for all "scientific and economic information" relied upon in preparing a section 3201(a)(5)(A) certification -- which is in turn required for all rules above a \$25

definition of major rule also includes amorphous terms such as "significant adverse effects" on a variety of factors. This invites unproductive litigation over whether rules qualify as "major."

- \* The bill seriously misapplies scientific concepts and inappropriately codifies methods for expressing scientific uncertainty. Perhaps the most egregious example is the bill's use and three-prong definition of "best estimates," each element of which is highly problematic. While it is appropriate to call for disclosure of scientific uncertainties, including those arising from lack of understanding of biological mechanism of action as well as range and distribution of both exposure and susceptibility, Title III as drafted is dangerously wide of the mark. It is urgent that Congress avoid enacting prescriptive legislation that shoves analysis of environmental and health policies into an ill-fitting straight jacket of misapplied scientific terminology.
- \* In addition, under Title III as written, it is not clear whether the courts would regard the risk assessment guidelines in and of themselves to be judicially reviewable. If so, we will have guidelines written by lawyers for lawyers rather than by scientists for scientists -- a pointless exercise.
- \* Title III also requires a massive peer review system to review an inordinately large number of activities. As a result, one of the most critical elements of peer review -- namely balance -- will be rendered virtually impossible, in light of the large number of industry-associated scientists relative to the availability of academic and advocacy-group scientists. Lacking balance, the peer review process will fail to improve agency decisionmaking. In addition, because peer review must be completed before regulations can be issued, the bill hands these panels a de facto veto power over new environmental and health protections.
- \* Furthermore, Title III potentially excuses agencies from carrying out mandatory duties imposed by other federal statutes -- mandates that were imposed when the public became fed up with agency foot-dragging on health, safety, and environmental matters. While bureaucrats ponder and jump through the procedural hoops imposed by Title III, pollution will continue unchecked. But Title III fails to balance the need for analysis against the need for timely action.

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million threshold.

- \* Finally, Title III takes a remarkably uncritical approach to cost/benefit analysis. The bill offers no means for reviewing or improving cost/benefit analysis. Indeed, Title III does not even acknowledge that cost/benefit analysis, like risk assessment, contains numerous uncertainties, assumptions, and data gaps. Yet while Title III requires agencies to communicate the uncertainties surrounding risk assessments, the equally great uncertainties for cost/benefit analysis remain hidden. Similarly, while the President is charged with issuing guidelines for risk assessments, no such guidelines are required for cost/benefit analyses.
- \* Most importantly, Title III fails to acknowledge other dimensions of decisionmaking in addition to monetizable costs and benefits. Title III disregards fundamental issues, widely acknowledged in the risk analysis community, such as the importance of the distribution of risk and benefit; the difficulty in applying discounting functions to health and safety issues; the beneficial impact of regulation as a stimulus to technological change and hence economic growth; and the additional values the public places on such "goods" as visibility, opportunities for future use, and trans-generational health effects, including cancer. Calls by some parties to extend Title III to preclude agency action in the absence of a positive cost/benefit analysis must be squarely rejected in light of this methodology's inability to reflect these legitimate, and indeed vital, societal concerns.

These and other problems in Title III are detailed below.

### **General and Conceptual Issues**

A fundamental flaw in Title III is its assumption that the major problem with current regulatory policy related to risks to human health, safety and the environment is a failure by federal agencies to apply the right methods. The "right methods" imposed by Title III are a combination of risk assessment, strictly defined as to methodology and application, coupled with cost/benefit analysis. Without a doubt, there are flaws in environmental policymaking (as in every realm of human endeavor), and EDF has not been silent about them. These problems are mostly due to the failure by all parties to encourage provision of critical information, and the failure by regulators and the private sector to respond expeditiously to scientific information on risk. Codification of strict principles and practices for risk assessment and cost/benefit analysis will not alleviate these continuing problems.

Title III assumes that our current state of knowledge and practice in risk assessment is sufficient to allow us to discern the "right" answers to complex questions about regulating risks, if only we could elicit consistent practice from regulatory agencies. The practices mandated by Title III, however, would limit the science of risk assessment to current understanding, impose rigid and unscientific definitions upon many aspects of risk characterization, and couple the uncertainties of risk assessment to the even less-tested methods of health and environmental cost/benefit analysis. Rather than improving the basis of risk regulation, Title III will hinder the evolution and application of scientific knowledge. It is fundamentally at odds with the recommendations of the distinguished National Academy of Sciences' Committee on Risk Assessment, which concluded its 1994 evaluation of risk assessment by recommending flexibility, responsiveness, and re-evaluation.

Regrettably, Title III does almost nothing to move us toward the day when "right" answers can be known, or at least estimated with less uncertainty. There are critical needs for better data on the toxicity of particular substances, the methods by which they act, and human and environmental exposure levels. To truly improve risk assessment, we must have better data to feed in, yet Title III misses this golden opportunity to create mechanisms to fill those gaps.<sup>8</sup>

Title III also conspicuously fails to take any steps whatsoever to improve cost/benefit analysis, or even to acknowledge that it, like risk assessment, contains numerous uncertainties, assumptions, and data gaps. Yet while Title III requires agencies to communicate the uncertainties surrounding risk assessments, the equally great uncertainties on the cost side of the equation remain hidden. Similarly, while the President is charged with issuing guidelines for risk assessments, no such guidelines are required for cost/benefit analyses. Title III does not even make any effort to provide for a better understanding of cost/benefit methods and practices (which, by notable contrast to risk assessment, have not been the subject of detailed studies by the National Academy of Sciences or other broad-based expert groups). At the

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<sup>8</sup> One such mechanism could include adoption of the Organization for Economic Cooperation and Development's requirement to produce a basic toxicologic data set -- known as the Screening Information Data Set -- for high-volume chemicals used in commerce. At the modest cost of \$60,000 or so, enough information is obtained to indicate whether the substance merits further investigation, or is likely to be innocuous. At present, U.S. policy simply assumes that no news is good news, irrespective of the demonstrable lack of scientific validity for such a stance.

same time, agencies are required to include "indirect" costs, regardless of the fact that methods for doing so are of questionable reliability.

Most importantly, Title III fails to acknowledge other dimensions of decisionmaking in addition to monetizable costs and benefits. Title III disregards fundamental issues, widely acknowledged in the risk analysis community, such as the importance of the distribution of risk and benefit; the difficulty in applying discounting functions to health and safety issues; the beneficial impact of regulation as a stimulus to technological change and hence economic growth; and the additional values the public places on such "goods" as visibility, opportunities for future use, and trans-generational health effects, including cancer.<sup>9</sup> In a comprehensive analysis, risk assessment and cost/benefit analysis are important tools but not the *only* relevant factors.

The limitations of cost/benefit analysis are highlighted by the few instances where analyses of both cost and benefits have been undertaken retrospectively. It is clear that we initially underestimated the benefits of action. For example, the enormous benefits that our society has reaped from the removal of lead from gasoline, starting in 1978, far exceeded all the estimates of what was originally regarded as a marginal contribution of this source of lead for human, particularly children's, exposure. In addition, we gained the additive benefits of cleaner urban air because lead-free gasoline enabled us to deploy the technology of the catalytic converter, to reduce car smog. Similarly, the banning of DDT in the early 1970s, one of the landmark events of American environmental policy, was undertaken primarily to protect birds from reproductive failure due to eggshell thinning; however, we now understand that the great reductions in human exposure to this toxic agent

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<sup>9</sup> In this regard, little has changed since the late 1970s, when two committees of Congress concluded that cost-benefit analysis remained limited in its ability to provide useful and reliable information to guide policy decisions. In 1978, the Senate Subcommittee on Government Affairs concluded that "it is extremely difficult to quantify benefits since they are subject to great uncertainty and often become apparent only with the passage of time. In addition, some important benefits -- such as recreational or aesthetic values -- are difficult if not impossible to quantify in any meaningful way . . . Therefore, there are serious limitations on the use of economic impact analysis in the health and safety area . . . Decisionmaking to protect the public from serious hazards should not be reduced to those terms." Study on Federal Regulation, Vol. VI, Senate Committee on Governmental Affairs, 96th Cong., 1st Sess. xxiv (1978).

may have positive benefits for reducing risks of breast cancer, as well as other ecological benefits.

Even if we had been perspicacious enough to identify these multiple benefits, we had and continue to have incomplete tools for assessing them economically. At present, EPA is engaged in a Congressionally mandated cost/benefit analysis of the regulations issued under the Clean Air Act; yet in a report to the Science Advisory Board, EPA staff indicated that most of the identifiable benefits could not be quantified. What is the benefit of reducing the severity of asthma attacks in susceptible children? The unit of analysis in most environmental cost/benefit analysis is lives saved, rather than lives improved. Yet to the parent of an asthmatic child -- and to his or her siblings, schoolmates, and friends -- the rewards of such action are real and valuable, and far exceed the costs of avoided medical treatments.

Cost/benefit analyses also fail to account for the fact that regulations themselves often prompt future technological developments that can reduce future compliance costs. For example, during debates on the Clean Air Act Amendments in 1990, some industry groups projected the cost of removing a ton of sulfur dioxide from utility emissions at \$1500, and EPA projected \$740/ton. But the actual price, as indicated by sales of tradeable emission credits, is currently \$140/ton -- a ten-fold decrease in less than five years. Absent the incentive provided by the new regulatory program, it is highly questionable whether these cheaper compliance strategies would have been developed. Initial estimates of cost can also be overstated as a result of unanticipated economies of scale, replacement of equipment or processes for unrelated reasons, and competition among industry.

Furthermore, while cost/benefit analysis can play a useful role in identifying the most-bang-for-the-buck options available on a society-wide basis, in the regulatory context there is often a major disconnect between theoretically available alternatives. Even assuming that everyone agrees, for example, that it is socially preferable to spend \$1 billion to expand childhood immunization programs rather than clean up factory air emissions, a decision not to require factory owners to clean up their emissions does not translate into higher budgets for immunization programs. Moreover, even universal immunization does nothing to reduce children's exposure to lead poisoning. Risks are not fungible; the task for policy makers is to ensure that *all* significant risks -- many of which interact -- are addressed.

One additional point warrants mention: although the lead-gas phaseout is often cited as a vindication of the utility of cost/benefit analysis, it is at least as much an indictment of it. Not until America had subjected its inhabitants

to more than a half-century of intensive lead exposure from gasoline did the scientific data catch up with the toxicologic reality of widespread exposure and neurotoxic impairment. As a result, both those who read this testimony and those who wrote it are all at least marginally less intellectually adept than we would have been had lead been banned from gasoline decades earlier. In short, while cost/benefit analysis can be a useful tool, it cannot serve as an exclusive basis for decisionmaking.

### **Particular Provisions of Title III**

#### **Risk Characterization Provisions<sup>10</sup>**

**\* Title III Will Encourage Misuse of Statistical Techniques** - In section 3105, Title III strays conspicuously from good science. While EDF agrees that risk characterizations should contain appropriate information on the range and distribution of exposures evaluated in the risk assessment, the manner in which section 3105 requires this information to be provided is wholly inappropriate. If adopted, this language will constrain scientific information to an inaccurate and misleading straitjacket of simplistic statistics. The bill calls for use of "upper bound estimates and central estimates." This is a junk science approach to a complex issue. The way in which the variability of risk estimates -- or any other scientific data -- can appropriately be presented depends on two factors: the design and conduct of the study producing the data, and the amount and type of data generated. It is unscientific to specify the type of statistical analysis or data presentation absent criteria relating to study design and data.

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<sup>10</sup> In addition to other problems, Subtitle A's highly detailed and prescriptive provisions would apparently apply to a wide array of materials, including public education documents aimed at lay audiences, since the term "risk characterization" is defined in section 3107(1) to include any "document which is made available to the public". The requirements of section 3105 are far too technical and abstruse to make sense in such contexts; they will hamper rather than promote public understanding. For example, it would be absurd to include in EPA's brochure "Lead Poisoning and Your Children" -- a brochure designed to be read by a wide audience including parents with limited educational backgrounds -- discussions of best estimates, exposure scenario assumptions, and detailed comparisons with other risks.

Central estimates are a particularly dangerous methodology for limited data sets and as a means of combining results of different analyses. Recently, EPA inadvertently demonstrated as much: when it attempted to "find" a central estimate among various estimates of the cancer risk of dioxin, the "center" of these estimates -- be it calculated as a mean, median, or mode -- yielded a number that was actually supported by **no** analysis.

If two risk assessments proceed from fundamentally different assumptions as to the underlying mechanism by which a substance exerts toxic effects, it is hardly surprising that their results differ. **Scientific disagreements over biological mechanisms of action cannot legitimately be papered over by averaging incompatible estimates**; while taking the average of two such different estimates yields an artificial "central estimate", this number has no basis in anything that can remotely be called science. It would be as if one were to average the winning percentage of all Los Angeles sports teams -- basketball, football, hockey, and baseball -- to derive a central estimate of likely success for an athlete playing in that city.

The range and variability of a scientific estimate reflects several factors, each of which deserves separate presentation and discussion. We support Title III's intention to make more transparent the analytic processes of risk assessment, but the result of this section will not be clarification.

In cases of national standards and regulations, it is imperative to take into account how both exposure and response vary among different subgroups and individuals within the population. Put simply, it matters not only what level of pollution is found in a city's air, but also how many asthmatics live there. Title III acknowledges variation in exposure while ignoring variation in response. Knowledge of the latter is generally used in public health to direct our resources towards the most vulnerable, and to those actions where investments will have the highest reward. For instance, we removed lead from gasoline to protect the health of children, based on our knowledge that differences in both exposure and response result in the greatest risks of lead toxicity in children under six years.

Title III is silent on important determinants of response, such as age, nutritional status, socioeconomic factors, pregnancy, and concurrent or prior disease. Even more troubling, its insistence on use of "most plausible" assumptions obscures these important variables. The meaning of the term "most plausible" is unclear and fraught with danger. For decades it was common practice to assume that the standard reference for understanding human physiology was the so-called "reference man" as defined by the World

Health Organization (e.g., a 70-kilogram male with the general biology of a Caucasian).

Since far less than half of the U.S. population fits this description, it is hard to see how this is a "plausible" assumption. Moreover, a substantial fraction of our population is likely to be at significantly greater risk than this "reference man" because of differences in intensity of exposure to environmental media such as air, water, food, and dust, and differences in absorption, metabolism, and response. Risk characterizations should present this range fully and accurately, with enough information to allow the public to evaluate the adequacy of proposed risk reduction measures to protect the most vulnerable members of our society.

**\* Title III Will Yield Simplistic and Misleading Risk Comparisons -**

Title III next falls into the trap of encouraging use of dangerously simplistic risk comparisons. Typically, comparisons fail to consider issues such as whether the risk is voluntary or involuntary, its impact, likelihood, cost effectiveness, maximum benefit, severity/irreversibility, environmental justice, and other concerns. Such comparisons often have their origin in tables such as those published by Crouch and Wilson and Doll and Peto, in which various risks are arrayed in simple tables of likelihood, or contribution to overall mortality. These comparisons -- for instance, the comparison between the likelihood of being killed in a car crash with the likelihood of contracting cancer from pesticide residues in food -- have been used by some advocates to argue against investments in preventing "low likelihood" risks. These comparisons are deceptive: risks differ in more than likelihood, and likelihood is related to the number of persons at risk as well as the expected frequency of adverse effect.

Thus, the likelihood of dying in a car crash applies to only those persons driving cars. Moreover, it is substantially modulated by such factors as drinking, age, sex, type of car, use of safety devices, and observance of speed limits. Car driving, even if highly dangerous, is also a voluntarily chosen activity. The likelihood of cancer associated with pesticide exposure in drinking water is possibly modulated by diet, other exposures, and host factors (including possible genetic susceptibility) of the individual. However, one cannot choose not to drink water, and selecting among sources of drinking water is often not based on any knowledge of carcinogenic risk -- no choice may be available and information on pesticide contamination may not be forthcoming, as recent revelations about the suppression of water quality test data in New York indicate. Many risks are age- and time-dependent, such as the risk of breast cancer in women and prostate cancer in men. For such risks, understanding the potential contribution of preventable causes must be

evaluated upon an age-stratified analysis of risk. That is why the cost/benefit ratio of mammography for women varies substantially with age, with the major benefits accruing to women over 50.

Squashing all these complexities into a single number for purposes of risk comparisons distorts reasonable public discourse. Some of the supporters of Title III complain that public debate on risk issues is ill-informed and emotional. But Title III will do nothing to improve the quality of public discussion.

### **Implementation Issues**

#### **\* Title III Will Encourage Unnecessary and Inappropriate Litigation -**

As written, the bill does not indicate whether the risk assessment guidelines can be challenged in court as arbitrary and capricious under the Administrative Procedures Act. Under existing case law, they might well be found to be reviewable. (It is clear that final agency rules would be challengeable as arbitrary and capricious with regard to their use of risk assessment techniques, as they are now.)

If they are, **risk assessment guidelines will end up being written by lawyers for lawyers (and judges), rather than by scientists for scientists.** The scientific complexities of risk assessments -- particularly in the context of general guidelines that will need to address a wide range of situations -- are likely to be given short shrift as a result. In addition, this approach will have the effect of retarding rather than encouraging incorporation of new scientific information into the guidelines, because changes will also be judicially reviewable -- agencies will be discouraged from revising guidelines because of the resource demands of making a "review" quality record and defending the litigation, not to mention the perils of potentially having to re-open regulations if the court finds anything in risk assessment guidelines to criticize.

**\* Title III Will Waste Taxpayer Resources -** The essence of Title III is the requirement that agencies prepare risk assessments and cost-benefit analyses for "major rules." That term is given a three-part definition as one that (i) has an annual economic impact of more than \$25 million; (ii) causes "major increase in costs or prices for consumers or industries"; or (iii) causes "significant adverse effects on competition, employment, investment (etc.)." All three parts of this definition are flawed.

First, the \$25 million threshold is unreasonably low given the analytic burdens imposed under this section. Doing cost/benefit analyses well requires

substantial time, data, and expertise; doing them badly is worse than useless, since bad analyses produce "answers" that have a spurious air of reliability that is misleading to the public and decisionmakers alike. EPA estimates that the cost of preparing cost/benefits analyses ranges from just over \$200,000 to more than \$2,300,000, averaging \$675,000.<sup>11</sup> A \$25 million threshold would apparently require that cost/benefit analyses be prepared for several hundred major rules developed by the wide range of agencies that regulate health, safety, and the environment, including at least the Departments of Transportation, Agriculture, Health (including the Food and Drug Administration), Interior, and Labor, as well as the Environmental Protection Agency and the Consumer Product Safety Commission. The annual cost to taxpayers is likely to be in the hundreds of millions of dollars.

It is worth noting that two Republican Presidents (Reagan and Bush) used a substantially higher threshold (even ignoring subsequent inflation) in defining rules as major for the purpose of triggering cost/benefit analysis: \$100 million as opposed to \$25 million. It is also worth noting that **\$25 million is only 0.0004% of the U.S. Gross Domestic Product** of \$6.3 trillion.

Second, the use of amorphous and undefined terms such as "major increase" and "significant adverse effects" creates an unworkable approach given that alleged noncompliance with this section may be judicially reviewable. Any person who does not like a rule that is not classified as "major" will be able to go to court and challenge the agency's failure to prepare the risk assessment and cost/benefit analysis, apparently irrespective of whether the rule would have come out differently had those analyses been done. This is simply promotion of wasteful litigation in the federal courts.

**\* Title III Will Promote Bureaucratic Inaction** - Section 3201(a)(5) requires that agency heads make a series of certifications before issuing a final rule. These certifications are inherently discretionary, such as whether the rule will "substantially advance" the statutory purpose and whether its benefits will "justify" its costs. This provision could have the effect of granting agencies complete discretion to circumvent existing statutory mandates and deadlines, simply by declining to issue a certification. Federal decisionmakers, like those in Congress, private industry and every other human endeavor, tend not to make decisions on complex or controversial issues unless they have a deadline. Congress has long recognized this basic fact, and has established deadlines for agency action in numerous contexts -- ranging from issuance of

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<sup>11</sup> U.S. EPA, Economic Studies Branch, Office of Policy Analysis. EPA's Use of Benefit-Cost Analysis 1981-1986. August 1987.

new regulations to action on applications submitted by industry. Indeed, House Republicans themselves recognized the need for action-forcing measures by imposing on themselves the 100-day deadline for action on the Contract with America.

It is possible that such promotion of bureaucratic inaction is an unintended consequence of an effort to require that heads of agencies disclose whether they believe that the discretionary tests set out in section 3102(a)(5) are met. If so, the bill must be clarified by adding a savings clause that makes clear that these provisions do not override existing statutory requirements. (The savings clause currently contained in section 3103(c) very clearly applies *only* to the risk communication provisions of Subtitle A, and not to section 3102(a)(5)).

If, however, the bill does seek to override current law, respect for the democratic process demands that it say so explicitly **and** indicate which deadlines are being obviated. Wholesale repeal of unnamed agency deadlines is not only poor public policy for reasons noted above; it is also a cowardly legislative approach. If Congress wants to dispense with deadlines it has already enacted in specific statutes, it should amend those statutes. Failing that, Title III must at least identify what provisions are being de facto amended.

Finally, failure to clarify the current language invites extensive litigation as to whether or not the bill is intended to override existing law. If Congress is serious about reducing unnecessary litigation, it should give lawyers less grist for their mills. To paraphrase the adage "charity begins at home," it's time for clarity to begin in the House.

Moreover, because one of the certifications is dependent on completion of peer review in many instances, this provision allows peer reviewers to exercise a de facto veto power simply by failing to complete their review. It is quite possibly unconstitutional to grant such authority to non-governmental personnel; it is unquestionably a bad idea to do so in any event. Further, as noted below, the bill as drafted makes it extremely likely that industry groups will dominate the peer review process, further exacerbating these concerns.

**\* Title III Will Divert Scientific Resources and Undercut the Integrity of Peer Review Processes** - (section 3301) - Scientists and economists who spend hours reviewing risk assessments and cost/benefit analyses are, by definition, not spending that time conducting basic or applied research, teaching, or otherwise engaging in core professional activities. While EDF supports the use of appropriate peer review, the bill as drafted conspicuously

fails to require use of peer review in the context in which it is most important -- namely, the risk assessment guidelines required under section 3106 -- and calls for it in a host of other contexts: not only to all rules with a projected economic impact of more than \$100 million, but also to all other "major" rules (see discussion above), *and* to any additional risk assessments and cost/benefit analyses which the Director of the Office of Management and Budget concludes "may have a significant impact on public policy decisions" (see section 3301(b)).<sup>12</sup>

In addition, peer review is required of "scientific and economic information used for purposes of any evaluation under section 3201(a)(5)(A)" (which in turn requires the agency to certify that evaluation of costs and risk reduction benefits is based on objective evaluation of all relevant information). Since the certifications must be made for all \$25-million-plus rules, this provision appears to effectively trump the \$100 million cutoff in section 3301(h). Moreover, the meaning of the clause "scientific and economic information" is very far from clear. Under the bill as drafted, peer review is likely to be carried out on a large number of relatively routine matters, wasting the resources of taxpayers and the scientific community alike.

Several other aspects of the peer review provisions also present grave problems. Because of its procedural features, the bill would fail to improve the use of scientific information within the federal government and would actually erode the credibility and usefulness of existing peer review mechanisms.

Specifically, the bill would be likely to produce panels stacked with industry employees and consultants, with few or no truly independent scientists. This would occur because (i) the bill contains only extremely weak language calling for the peer review panels to be balanced "to the extent feasible"; (ii) there are no provisions to compensate scientists for their time spent serving as peer reviewers; (iii) the bill **forbids** exclusion of individuals on the ground of conflict of interest; (iv) the language requiring use of "external" experts could be interpreted as barring the participation of federal scientists

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<sup>12</sup> The Director is mandated to require peer review upon making this determination. As with several other provisions of the bill, it is not clear whether someone who believed the OMB erred in not requiring peer review of a particular risk assessment or cost/benefit analysis would be able to litigate that matter.

from other agencies.<sup>13</sup> In short, scientists who are directly employed by the industry being regulated, or those in consulting firms hired by industry for the sole purpose of participating in the panel, would be allowed to participate and apparently even to form a majority of the panel as long as their interests are disclosed to the agency (but not necessarily to the public). This is a case of inviting the fox to guard the chicken coop.

Why does that matter? Because it can confidently be predicted that the "majority" peer review reports will be cited as somehow authoritative by those wishing to influence agency decisions, or to criticize them in the courts, the Congress, or the media. Indeed, if such reports are not supposed to have any effect there is no point in creating them. They must not be a mechanism for allowing industry scientists a supposedly neutral forum for disseminating their views; industry comments should be labeled as such. Unbalanced peer review is antithetical to the purpose of the entire process.

Finally, the complete absence of a time line for completion of peer review could allow reviewers to stall regulatory action indefinitely simply by failing to submit a report.

### **The Confused Relationship of Title III and Title VII**

The intended relationship between Title III and Title VII of H.R. 9 is obscure at best. For example, how does section 7004(c)(6)'s requirement to prepare a statement that "quantifies the risks" relate to the risk assessment provisions of Title III? It appears that the lower thresholds in Title VII -- namely a regulation that entails \$1 million in costs, or affects 100 people<sup>14</sup> -- effectively override the higher threshold in Title III for preparation of a risk assessment, thus exacerbating the waste of taxpayer resources identified above.

Similarly, how do these requirements of section 7004(c)(10) & (11) to prepare "an estimate of the economic costs" and "an evaluation of the costs versus the benefits derived from the rule" relate to the cost assessment and cost/benefit provisions of Title III? Here also, the lower thresholds in Title VII

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<sup>13</sup> Current practice allows federal scientists from other agencies to participate on peer review panels. It should be made clear that this practice is allowable.

<sup>14</sup> One hundred people constitutes 0.000038% of US population; \$1 million constitutes 0.000016% of the gross domestic product).

would appear to override the higher threshold in Title III for preparation of a cost/benefit analysis.

Finally, how does section 7004(c)(11)'s requirement to evaluate how benefits "outweigh" costs relate to Title III's requirement for certification that benefits "justify" costs (see section 3201(c)(5)(C)? As already noted, cost/benefit analysis is too limited a tool to make it the only criterion for deciding whether to regulate health, safety, or the environment, since it ignores distributional effects, future technological developments, and a host of other variables.

### **Conclusion**

In addition to the key concerns laid out above, Title III suffers from many additional flaws. The findings contain both misleading statements and serious omissions. Furthermore, the bill contains numerous ambiguities that must be resolved in the interests of good government as well as good science. These important issues must be resolved as an essential part of consideration of this bill.

Thank you for the opportunity to present our views.

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**INVESTING IN PREVENTION:**

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OPPORTUNITIES TO REDUCE DISEASE  
AND HEALTH CARE COSTS THROUGH  
IDENTIFYING AND REDUCING  
ENVIRONMENTAL CONTRIBUTIONS  
TO PREVENTABLE DISEASE

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**A REPORT TO THE  
HEALTH CARE  
REFORM COMMISSION**

Ellen K. Silbergeld, PhD



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**A REPORT TO THE HEALTH CARE COMMISSION**

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May 15, 1993

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## **PREFACE**

In the current debate over U.S. health care reform, the intense focus on cost containment and financing alternatives is obscuring the larger question of how America — no matter who pays — can provide its citizens with an affordable and accessible system that improves medical care, prevents disease, and promotes health.

The medical community recognizes the importance of disease prevention in health care and health promotion. Increasingly, we acknowledge the importance of determining and preventing environmental hazards in disease occurrence. In the health care reform process, policymakers have an unprecedented opportunity to institute in a program of cost-effective health safeguards particularly those which address environmental hazards.

Broadening public access to doctors, nurses, and hospitals is not sufficient to prevent environmentally caused disease. Effective disease prevention requires us to deliver services that are needed before they are demanded. Indeed, the medical care system must provide an early warning system for environmental health hazards — alerting public health and regulatory authorities who can eliminate hazardous exposures at the source. Moreover, medical professionals must be trained to be alert to and identify unexplained signs and symptoms that may be due to environmental or occupational exposures.

On the other side, a reformed medical care system must support public health authorities. Just as discoveries by the medical care system require follow-up by public health authorities to eliminate exposures in workplaces and the environment, discoveries by public health authorities require follow-up by the medical care system that can evaluate and treat illnesses. When public health authorities suspect that a particular population is being exposed to an environmental hazard, the medical care system must be ready to find and evaluate people at risk. Clearly, a medical care system which can detect, report and treat environmental illness will remain ineffective

without an adequate public health system which can prevent further exposure to hazards before disease occurs.

Toxicology testing has been completed on fewer than one half of the chemicals used regularly today. New research and testing techniques will help us to identify previously unknown hazards — many of which may be amenable to early interventions and cures. Thus the task of finding and evaluating populations of exposed individuals will grow. Medical care reform must be designed to incorporate this function. The practice of medicine must be firmly and permanently linked to implementation of public health and preventive measures. The public health community — including researchers in environmental health — must be developed to provide this critical support.

The following report summarizes three areas where attention to environmental causes of disease can increase the benefits of disease prevention. In each of the three areas — lead poisoning, asthma, and low birth weight — attention to environmental factors will directly lower treatment costs and improve health outcomes.

Surveillance and monitoring programs need support, not only to alert us to health problems, and their causes, early and reliably, but also to provide us with indicators to measure the success of our new health care system.

The reform of the U.S. health care system allows us, for the first time, to apply universally sound prevention and protection principles to this country's medical practice. And this prescription for health care reform cannot wait.

Ellen Silbergeld Ph.D.  
Environmental Defense Fund  
Toxic Chemicals Program

Anthony Robbins M.D.  
Physicians for Social Responsibility  
Board of Sponsors

**INVESTING IN PREVENTION:  
OPPORTUNITIES TO REDUCE HEALTH CARE COSTS THROUGH  
IDENTIFYING AND REDUCING ENVIRONMENTAL CONTRIBUTIONS  
TO PREVENTABLE DISEASE**

**Introduction**

Among the cost-effective interventions to reduce the burden of health care costs upon individuals, the private sector, and government, prevention of disease is an important option. The risks of many diseases can be reduced through health promotion, early identification, and effective delivery of primary and secondary prevention. This report summarizes three areas where attention to environmental causes of disease can increase the benefits of disease prevention. "Environment" is a broad term that can mean, at its most fundamental, all those factors that are not heritable by the individual; in this report, we define "environment" operationally, as those factors generally under the purview of the Environmental Protection Agency, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission — that is, agents and factors external to the individual, other than foods (diet in general), drugs, and cosmetics. We include in "environment" such factors as pesticides, toxic chemicals, and radiation, as these appear in the media regulated by the EPA (air, water, drinking water, some foods — such as freshwater fish — and land), the occupational environment, and in consumer products. This definition is for the convenience of policymaking, and does not imply that we consider other types of environmental factors — such as cigarette smoking — to be of lesser importance.

This report draws upon extensive research by EDF and other entities on the major diseases affecting the U.S. population. Among these, we have selected lead poisoning, asthma, and low birth weight as health outcomes where attention to environmental factors may direct prudent investments in prevention and changes in health care delivery. We do not imply that this focus will completely prevent all cases of dis-

ease (except in the case of lead poisoning, where all cases are due to environmental exposures), but rather that an investment in environmental factors is likely to be cost-effective. The major portion of this paper presents recommendations for preventing lead poisoning; this relative imbalance reflects the fact (as noted above) that lead poisoning is an entirely preventable disease whose cause is wholly environmental. Moreover, considerable analysis of opportunities to prevent lead poisoning has been undertaken by government and nongovernment agencies.

Asthma and low birth weight are considerably more complex conditions, for which our knowledge of etiology is incomplete. There are likely to be significant contributing causes other than those we have included in our definition of "environmental". Asthma in particular is highly correlated with environmental quality, more broadly defined: dust mites are major allergens, for instance. However, there are only limited opportunities for preventing exposure to such agents through federal investments in health care. For that reason, attention to those factors that are feasible to control may be even more important.

In the final section, we note areas for critical research, where targeted investments could increase our knowledge in the short-term and support redirection of health care resources. There is a much larger agenda of needed research in environmental health, as noted by the 1992 Carnegie Commission report on this subject, but that is beyond the scope of this report.

It is not a coincidence that the issues we have identified as being potentially most rewarding in terms of an investment in environmental health are diseases and conditions that affect women and children, nor is it by chance that these conditions disproportionately affect the disadvantaged in our society. Women and their children are disproportionately represented among the poor, as noted by many reports. Women and children are in many (although not all) instances susceptible to environ-

mental impacts because of behavior (in the case of children and lead) or physiology (in the case of low birth weight), particularly related to reproduction and development (and children may bear the burden of impacts experienced by their fathers as well as their mothers). This susceptibility may involve increased opportunities for exposure in these groups, increased absorption, and special vulnerability of target organ systems.

As shown in Table 1, many health problems occur more frequently in low income children, as compared to others. Because women and children are overly represented among the poor and disadvantaged in our society, they are also included among those populations most at risk for living in polluted environments and they are often most exposed to environmental hazards, as Bullard and others have noted in studies of environmental racism. Interactions with undernutrition and lack of access to preventive care — problems encountered by poor families — often compound the health risks of environmental hazards, such as lead.

**Table 1. Frequency of Health Problems in Children from Low Income Families, as Compared to Other Children<sup>a</sup>**

health problem	frequency among poor children
low birth weight	double
asthma	higher <sup>b</sup>
lead poisoning	triple
neonatal mortality	1.5 times
postneonatal mortality	2-3 times
conditions limiting school activities	2-3 times
severe anemia	double

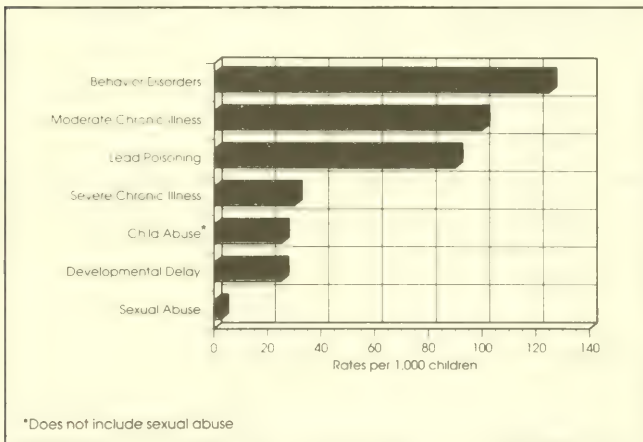
<sup>a</sup>Data from Starfield, in Behrman (1992)

<sup>b</sup>See text for discussion of estimates

## I. Lead Poisoning

Lead poisoning is now generally recognized as the most significant and prevalent preventable disease of children associated with the environment (see ATSDR, 1988; CDC, 1991; American Academy of Pediatrics, 1993). As shown in Figure 1 (from Perrin et al, in Behrman, 1992) lead poisoning is one of the new (or, more accurately, newly acknowledged) morbidities of childhood. Of course, lead poisoning may also be a significant cause of behavior disorders and developmental delay (see for instance Needleman et al, 1991) and thus contribute to two of the other significant "new morbidities" of childhood.

**Figure 1. New Morbidities of Childhood (from Perrin, et al "Health Care Services for Children and Adolescents" in Behrman (1992))**



Source: U.S. Department of Health and Human Services. *Healthy People 2000 National Health Promotion and Disease Prevention Objectives*. Washington, DC: U.S. Government Printing Office (DHHS PHS 91-50212), 1991; Newacheck, P.W., and Starfield, B. Morbidity and Use of Ambulatory Care Services Among Poor and Non-poor Children. *American Journal of Public Health* (1988) 78:927-33. Published in *The Future of Children*, Behrman, R., ed vol.2, no.2, Winter 1992 p.61

Part of the problem in failure to deliver these services lies in the lack of enrollment of all eligible children in Medicaid covered EPSDT programs, and part of the problem relates to continuing inadequacies of resources to screen children in a timely manner. Between 10 and 25% of all children less than 18 yrs are uninsured part or all of the time, and of these, the largest numbers are poor children from large families (Behrman, 1992). The attitude of some health care providers, to deny the risks and prevalence of lead poisoning, has also hindered some state and local programs, as in California and Washington state.

Problems with Medicaid and health insurance are beyond the scope of this study, but they impact upon the availability of lead screening in tertiary and other prevention strategies. In cities like Chicago and Baltimore, while screening efforts have been increased over the past two years with additional resources being made available to CDC and through CDC to the states and cities, we are far from screening all at-risk children (EDF, 1992). Recent experience in Baltimore, Cleveland, and Providence has shown that as screening efforts are implemented, more intoxicated children are identified.

**The minimum goal for tertiary prevention is the identification of all cases of disease.** As part of the conditions for receiving HUD and CDC funds for lead poisoning programs, each state and city should be required to develop strategies for identifying and reaching high risk populations, in cooperation with CDC, including door-to-door surveys and screening, intensive public education, cooperation with community groups, collecting ethnographic information to aid in implementation, and integration of lead screening with other health care delivery programs for these children (see below).

#### **b. case management**

Case management involves three types of response: medical, environmental, and housing. The complex involvement of health, environmental, and housing agen-

cies in responding to cases of lead poisoning compounds the problems of case management. Medicaid does not pay for lead paint abatement or alternate housing, although new HCFA guidance specifically authorizes reimbursement of costs involved in **detecting** environmental sources of lead for a poisoned child (AECLP,1993).

**To alleviate some of these problems of coordination and funding, case identification should precipitate establishment of a case management fund, into which the coordinated resources of Medicaid, HUD, CDC, and local sources should be combined and coordinated. Flexibility in utilizing these federally funded programs should be encouraged.**

Medical response is based upon the CDC recommendations for treatment and interdiction of further exposure (see AAP, 1993). At present, options for treatment are relatively limited (chelation treatment is recommended as efficacious only for children with blood lead levels  $>40$  mcg/dl); a new NIH-funded multicenter clinical trial on the use of DMSA in children with lower blood lead levels may provide data to revise these recommendations. In any event, exposure must be prevented in the presence or absence of treatment; continued lead exposure during chelation treatment is contraindicated since the drugs may actually facilitate uptake of lead.

The environmental and housing response is directed towards preventing further exposure, which requires identification of the source of lead for the case, and removal of the child from the leaded environment or the lead from the child's environment. Source identification usually requires coordination among health, environment, and housing agencies. From state to state, the degree of such coordination differs (see EDF report, 1992). Funding from HUD and CDC is supporting better integration and planning among these agencies, but there is urgent need for improvement, particularly in those states with relatively less experience in responding to lead poisoning. There are legal impediments to the prompt prevention of exposure, particularly when the source is the child's house. The child's family may in many cases

have few options for affordable alternate housing; the landlord may have little economic incentive to invest in abatement in marginally profitable housing. There is unfortunately often more incentive to remove the family from the house than to abate the hazard, since abatement is usually linked to the case. Once the case: source linkage is severed, by the child's relocation from the house, there is a reduced obligation to abate. Yet nothing is done to prevent the cycle from repeating, if another child moves into an unabated residence. Not until that second child is poisoned is attention refocused upon the source. Attempts at solutions at the local level have involved the establishment of "safe housing" where families can move while their residence is being abated; use of rent escrow provisions in landlord:tenant law, to provide financial relief for the tenant and an incentive for the landlord; supplying low-interest loans to low-income property owners; reducing the technical requirements of abatement to those related to the immediate hazard of readily available lead paint dust. These approaches need to be evaluated in terms of local experience.

## **2. Secondary Prevention - Prompt Identification Through Screening of High Risk Children for Lead Exposure**

Secondary prevention requires early identification of persons at risk before severe or overt clinical disease has been induced. Because of the prevalence of elevated lead exposures in young children, CDC and the American Academy of Pediatrics have appropriately recommended that all children should be screened for blood lead levels by the age of 2 years (CDC, 1991; AAP, 1993). Implementing this recommendation is far from complete, however, as shown in Table 2. Even in Baltimore, where the nation's oldest lead poisoning program exists, current screening rates are only about 50% (Patz, personal communication). There are three primary obstacles to introducing universal screening, not all of which are unique to lead screening: education of health care providers; reimbursement of screening costs; and low cost, rapid screening methods. As we solve the overall issue of delivering basic health care to all chil-

dren (through such programs as universal inoculations), lead screening should be incorporated through the following strategies:

**\*Lead tests should be fully reimbursable under all health care plans, private and public.**

**\*At any opportunity at which a child presents to the health care system, at any level, it should be ascertained that the child has been tested for lead.** In a recent study conducted through the emergency room at University Hospital in Baltimore, it was determined that the majority of young children had never been tested for lead prior to an emergency room (ER) visit. Lead tests were done at that point, and approximately 25% of the children tested in the ER were found to have blood lead levels >20 mcg/dl (a level requiring individual medical attention, according to CDC). As long as the ER remains a critical component of primary health care for at risk populations, this approach should be generally instituted, in terms of identifying children for screening, and offering screening as part of the diagnostic workup in the ER (whether or not related to the presenting causes).

**\*Lead tests should, as a last resort, be required for school entrance, with particular emphasis on entrance into preschool programs, given the higher risks of younger children (<3 yrs for exposure and toxicity).**

**\*Ancillary programs, such as AFDC and WIC, should also be utilized to identify high risk young children for screening, as well as providing opportunities for education and primary prevention (see below).**

**\*In order to determine success of prevention programs at all levels, lead poisoning should be a notifiable disease, and results of all lead screening tests should be reported in a uniform, computer coded manner through state health departments to the CDC.**

### 3. Primary Prevention - Abating Lead Hazards Before the Child is Intoxicated

Primary prevention programs are the most effective methods of disease prevention because they focus upon the vector or cause of disease rather than the target (the individual). In the case of lead poisoning, the cause of the disease is known: lead. The vectors are well-identified (see ATSDR, 1988) on a national and local basis. HUD and EPA have recently investigated the distribution of lead hazards, related to housing, in U.S. cities and towns. A very high priority should be placed upon the accurate identification of these hazards, and an integration of our knowledge of the distribution of lead based paint in housing with information on housing condition and demographics. With these data, it is possible to map the coincidence of source and receptor, as has been done in New Jersey using methods developed for geographic information assessment (GIS) (Wartenberg, et al, 1993). GIS methods may not be useful in all settings, but they have demonstrated utility in many older cities with so-called "lead belts" of older housing now in disrepair.

This information should provide the basis for primary prevention strategies, which utilize all tools of policy — information, intervention, and abatement — prior to the interaction of a child with the hazard.

Intensive research is currently under way, with HUD sponsorship, on cost-effective methods of hazard reduction with respect to lead based paint. This research must be rigorously evaluated in terms of short and long term cost-effectiveness. Delaying the interaction of children with lead based paint, through "in-place management" approaches, may appear cost effective in the short term, but this is the strategy that has resulted in the epidemic of lead poisoning now being experienced in many urban populations. Anticipatory strategies — methods to identify the likelihood of older housing becoming an immediate hazard **before** exposure occurs — are urgently

needed in order to expand our efforts from abating the first tier of present hazards to the larger set of housing containing lead paint not currently in conditions promoting absorption of lead by children. HUD's mandate to develop a hazard reduction strategy should be carried forward, with coordination into health care delivery programs as described above.

#### **4. Improving the Resource Base for Lead Poisoning Prevention**

A number of proposals have been made to increase the resources available to local agencies to implement the mandates for screening, environmental source identification, and lead abatement. The costs involved in full implementation are clearly in the multibillion dollar/year range. The costs of abating lead paint in older housing present an enormous burden on the private sector and on local government agencies. Recent appropriations by Congress to HUD, CDC, and EPA have provided substantial, but still far from adequate, funding for health, environmental, and housing response. Local funding sources are not available; after lead poisoning prevention programs were rolled into the public health block grants in 1981, state expenditures in most cases decreased precipitously over the first part of the 1980s. They have not recovered.

Private sector funding has been mostly on a case-by-case basis, and predicated upon the finding of a case of lead poisoning in those jurisdictions where local or state law mandates abatement by the homeowner or landlord. This provides no incentive for prevention. Although experiments are under way in Baltimore to leverage incentives for preventive abatements through reduced liability and other provisions for landlords, this is unlikely to provide full funding for all lead hazards.

**The Environmental Defense Fund has proposed (EDF, 1991) establishment of a dedicated fund, financed through fees paid on lead as it enters commerce, which would provide funding resources to state and local lead poisoning programs. (Florini & Silbergeld, 1993).**

This proposal is analogous to funding mechanisms used in California to derive resources for anti-smoking public health education by levying a fee on cigarettes. This proposal should be enacted.

## **II. Low Birth Weight**

Low birth weight — a category of outcome that includes infants with birth weights below 2500 gm, and extremely low birth weight infants — is a major health problem in the U.S. The prevalence of low birth weight in the U.S. is estimated to be between 5-10% (IOM, 1985), or between 150,000 and 300,000 infants per year. Low birth weight is a critical signal of events prior to birth, related to the health of the mother during pregnancy, and is a predictor of children's development and later health status, including the risk of neonatal mortality (IOM, 1985). A comprehensive national study of perinatal status and long-term outcome, conducted by NIH in the 1960s and 1970s, confirmed the significance of birth weight as a key event in the growth and development of children.

As shown in Table 3, low birth weight is a risk factor for other conditions, including asthma and learning disabilities. Thus, one risk may predispose for another, adding to the complexity of understanding attributable risk. Low birth weight may represent an early signal of potentially more serious events, with increased exposures, such as birth defects.

**Table 3. Birth Weight and Health Conditions at School Age<sup>a</sup>**

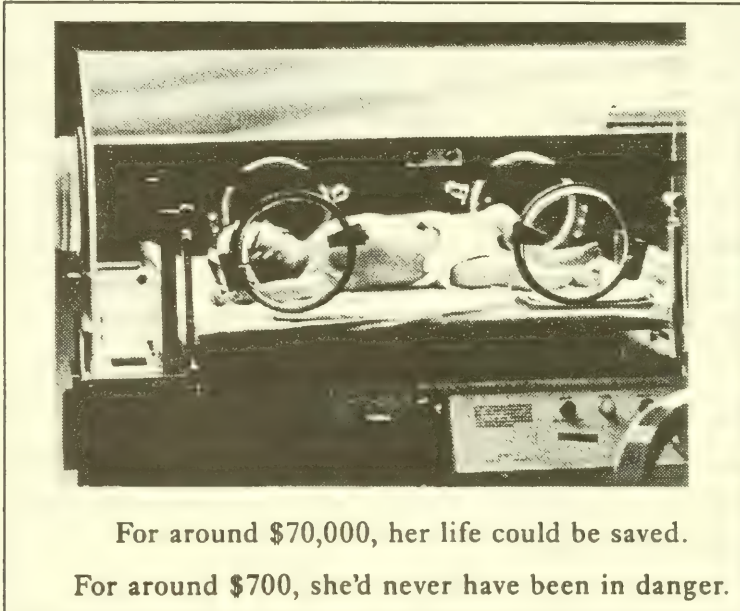
health condition	birth weight		
	<1000 gm	1501-2500 gm	>2500 gm
asthma	17.1% <sup>b</sup>	11.7	11.1
learning problems	24.8	13.0	10.5
IQ < 70	13.3	4.8	0.0
behavior problems	29.2	29.4	21.2
other conditions	23.6	16.3	9.8

<sup>a</sup>Data from McCormick et al (1992).

<sup>b</sup>Percent of children for whom conditions were reported; in these conditions, there was a significant difference across birth weight groups.

The costs of low birth weight are very great, as shown anecdotally in Figure 2. The **immediate** costs of managing a low birth weight infant immediately after delivery range between \$30,000 and \$70,000. Long-term costs may be 5-10 times this amount.

**Figure 2. Costs of Low Birth Weight, as Suggested by Private Sector Insurance<sup>a</sup>**



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Low birth weight may be associated with intrauterine growth retardation and/or with reduced gestational length (premature delivery) (IOM, 1985; Kiely, 1991). Intrauterine growth retardation is highly associated with lack of adequate prenatal care, poor maternal nutrition, history of low birth weight and miscarriage, and with

exposures to toxic chemicals (including maternal smoking and alcohol consumption) (IOM, 1985; Behrman, 1992; Kiely, 1991). Low birth weight is twice as frequent among low-income children as among higher income children, as shown in Table 1.

Improving programs for delivering prenatal care will undoubtedly be an important part of health care reform (Behrman, 1992). The economic returns on this investment are among the best documented in all of preventive medicine. In designing these programs, it is important to include opportunities to identify and prevent potential occupational and environmental exposures that may cause or contribute to low birth weight (also see section on surveillance, below).

Among the environmental agents that have been associated with low birth weight, exposures to lead, PCBs, solvents, and pesticides have been reported in several studies (Silbergeld and Tonat, in press; Stallones, et al, 1992). Sources of exposure to these agents often occur occupationally or via the diet (Hovinga et al, 1993). Dietary exposures to PCBs, lead, and pesticides have been intensively studied as risk factors for low birth weight (for instance, Rogan, et al, 1986). Several studies associating PCB exposure with lowered birth weight demonstrated the importance of exposure via consumption of contaminated fish. **This indicates an important opportunity for dealing with this contributing factor through revising water quality standards and guidelines for restricting the consumption of freshwater fish from contaminated ecosystems.** Current fish advisories are not generally set with regard to the potential susceptibility of pregnant women or to the variations in diet among subsets of the U.S. population. In many instances, the rural and urban poor rely upon freshwater fish for a significant portion of their protein intake. As found by EDF, polluted rivers, lakes, and streams in the U.S. are under-posted by state and federal authorities. Yet EPA recently criticized state agencies for posting some watersheds, on the grounds that the average cancer risks posed by fish consumption were not significant. However, EPA's analysis of risk was based upon average estimates of fish consump-

tion, without consideration of regional or population variances that could place persons at increased risk. Of particular concern are the consumption patterns among the urban poor and native Americans, who rely upon freshwater fish supplies. Low birth weight is more prevalent among many of these populations. **Particular attention should be paid to assessing dietary risks for pregnant women from these sources, and increased efforts to prevent contamination of this important food resource should be incorporated into EPA's activities under the Clean Water Act.**

Adolescents are at higher risk for premature and underweight infants, in many cases because of relatively poor maternal nutrition, intercurrent infections, and poor access to prenatal care (Behrman, 1992). More than 5 million adolescents lack health care (Carnegie, 1992). In some instances, these young women may still be at high risk for lead exposure — they are often just slightly beyond the ages of highest risk for contacting and absorbing lead. Adolescent mothers are also at risk for undernutrition. Possibly as a result of this, it has been reported that pregnant women under the age of 20 mobilize more bone mineral during pregnancy than do older women (Silbergeld, 1991). If these young women have been exposed to lead chronically over childhood, they may carry substantial body burdens of lead in their bones. Pregnancy may cause this stored lead to be mobilized from bone into circulation, affecting the health of both mother and fetus. **Considerably more attention needs to be paid to the sources of lead exposure for older children (>6 yrs) in order to assess the magnitude of this at risk population.**

### III. Asthma

Asthma is one of the most significant chronic diseases of childhood. The 1988 National Health Interview Study on Child Health indicated that 4.3% of all children younger than 17 yrs have asthma (Halfon and Newacheck, 1993) and over 10% of all Americans have asthma (NRC 1993). Black children have more than a 20% higher prevalence than white children (see Table 4). Asthma is the most frequent cause of pediatric emergency room use and hospital admissions, with some 500,000 hospitalizations per year (National Asthma Education Program, 1991).

**Table 4. Prevalence of Asthma in Children, 1988<sup>2</sup>**

	<u>Cases per 100 population, Per Cent</u>		
	All children	Poor	Non poor
All children	4.3	4.8	4.2
White	4.1	4.6	4.1
Black	5.1	5.2	5.1
0 - 5 yr	3.2	4.2	3.1
6 - 11 yr	5.1	5.6	5.1

<sup>2</sup>Data from Halfon and Newacheck (1993).

Asthma is an extremely costly disease, to society and to families, and the costs fall disproportionately upon the poor. The most recent economic evaluation of asthma in the U.S. estimated costs at \$6.2 billion/yr. Over 50% of this economic impact was associated with emergency room use and hospitalization, with the largest single direct medical expenditure, \$1.6 billion, for inpatient services in 1990 (see Table 5). There are also significant indirect costs imposed by asthma: it is the leading cause of significant school absences, and it imposes economic costs on parents and caregivers who must miss work to attend to sick children (Table 5).

**Table 3. Costs of Asthma, 1990**

direct medical expenditures <sup>a</sup>		amount
category		millions of \$
hospital care		
inpatient		\$1,559.6
ER		295.0
outpatient		190.3
physicians' services		
inpatient		146.0
outpatient		347.0
medications		1,099.7
<b>TOTAL</b>		<b>\$3,637.6</b>
indirect costs <sup>a,b</sup>		
category		impact
caretakers' lost time from work		\$889.7 million
school days lost		10 million/yr
percent of family income		2-30%

<sup>a</sup>Data from Weiss et al (1992), estimated on the basis of 1985 data<sup>b</sup>Estimated by Evans (1992)

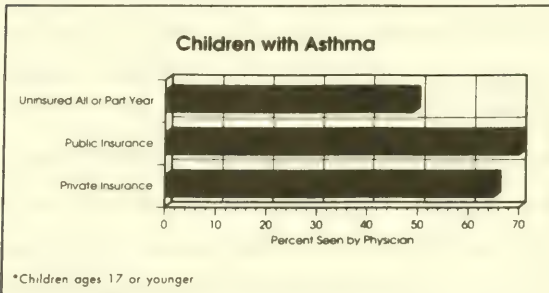
Over the past 20 years, the prevalence of severe asthma has increased significantly, with the largest increases occurring in poor, urban populations (NCR, 1993). Prevalence has increased 33% from 1970 to 1986, and 29% from 1980 to 1987; thus the increase is not solely due to changes in diagnostic classification (Buist and Vollmer, 1990). Hospitalization rates for children under 18 yr rose 4.5% per year during the last decade, and asthma mortality increased 6% per year over the period from 1980 to 1990 (Marder et al, 1992). According to the NHANES II survey (1976-1980), asthma is more than 20% more prevalent among blacks as compared to whites, and minority children appear to suffer more severe cases of asthma, according to hospital records (Marder, et al, 1992; Weiss, et al, 1992b; Wissow, et al, 1988). These children are also subject to underdiagnosis and decreased use of preventive care for asthma, which may contribute to increased severity of cases and increased reliance upon emergency room care and need for hospitalization (Wissow, et al, 1988b).

These changes in prevalence and mortality, particularly among the young, as well as the detection of small geographic areas where mortality rates are very high (Weiss and Wagener, 1990) "raise the important question of the role of the urban environment in asthma mortality, and specifically why the economically disadvantaged are at greatest risk" (Buist and Vollmer, 1990).

The management of asthma represents one of the starkest failures of current health care delivery. As shown in Figure 3, a large proportion of children with asthma are uninsured all or part of the time (Behrman, 1992). These data also indicate that less than half of the children without insurance saw a physician, as compared to rates of 65% of those with private insurance and 70% with public insurance. Given the importance of follow-up medical care in preventing recurrent severe asthma attacks requiring hospitalization, this is an important indicator of the reasons for the high cost of managing asthma through the emergency room.

In a study in Baltimore, over 50% of inner city school children reported that they received medical care for asthma only at an emergency room; less than one-third of those children reporting continuing symptoms and medication use had any follow up medical care and about one-fourth of these children had another ER visit (Weiss, et al, 1992b; Butz, et al, 1991; Wissow et al, 1988). One can conclude that effective delivery of prevention for asthma is rare, even after an index case of severe asthma.

**Figure 3. Children's Health, Health Insurance Status, and Use of Physician Services for Specific Conditions, 1987\***



Source: Agency for Health Care Policy and Research, 1987 National Medical Care Expenditure Survey: Child Health Questionnaire and Household Survey.  
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The greatest relative increase in asthma has occurred in persons on Medicaid. As noted above, many cases are treated in the emergency room, which incurs very great costs. Moreover, this method of care is frequently ineffective, since a significant number of persons admitted to the emergency room for asthma die in the ER because they are seen too late (Butz, et al, 1991). ER management can be effective for treating acute distress, but the patient usually returns to the setting that triggered asthma. Therapeutic intervention, such as steroids, act to decrease inflammation or the lung's reaction to a trigger. However, medication does not ameliorate the triggering events themselves.

Since asthma is a disease that cannot at present be cured, management and follow-up are critical to prevent recurrence of acute attacks and lower the risks of mortality. Thus the picture described above is a serious indictment of present failures to deliver effective health care.

Attention has focussed upon the prevention of acute attack and reducing the risks of mortality through improvements in the home environment and increased

follow-up. The delivery of better care to asthmatics has been underevaluated, particularly for inner city populations. A major project at seven medical centers, including Johns Hopkins in Baltimore, is examining strategies of increasing compliance with treatment, and self-evaluation/education, to reduce utilization of the emergency room for primary care (Eggleston, personal communication). Investments in developing these strategies are clearly appropriate: a 1986 study reported that a home asthma management teaching program targeted to a population of low income children with asthma, realized a savings of over \$11 for each \$1.00 spent to deliver health education (Clark, et al, 1986). Similarly, a study in Baltimore demonstrated that intensive programs of case management, education, and parent contact reduced ER acute care utilization by 50% (Wissow, et al, 1988). A 2:1 return on investment was reported in another study teaching self-management skills to children and parents, involving additional prescription drug use and intensive education (Rutten-Van Molken, et al, 1992). These programs clearly need additional support and incorporation in major programs of health education and disease prevention.

In addition, there are clear opportunities for reducing other factors that contribute to asthma. Prevention has been underinvestigated in studies of asthma. Primary prevention of asthma is difficult, since its causes in many cases are unknown. Asthma is now recognized as a chronic, rather than episodic lung disease, characterized by airway hyperresponsiveness, or increased sensitivity to triggers; airway obstruction or narrowing, which results in breathing difficulties; and airway inflammation. The presenting symptoms of asthma — shortness of breath, wheezing, tightness in the chest, and cough — may vary, and in some cases may only occur when respiratory infections are present. Sensitization of the individual is a chronic response, which then conditions the response to triggers, or precipitating agents (aeroallergens). Because of the prevalence of both sensitizing and precipitating factors, removal of all these agents from the human environment is usually impossible.

Environmental conditions have been extensively studied as contributing factors to asthma. Secondhand tobacco smoke, dust mites, cockroaches, rats, cats, dust, and pollen are well studied sources of antigens (NCR, 1993). In addition, major air pollutants are also factors. It is not clear if air pollutants cause asthma to develop, but chronic exposure to low levels of certain air pollutants may induce episodes of bronchoconstriction and increase hyperreactivity in persons already sensitized (Tseng and Li, 1990; Tseng et al, 1992). Large scale population studies, geographic analyses, cohort studies, and even clinical experiments have supported an association between asthma incidence and the air pollutants  $\text{SO}_2$ , particulates, and ozone (for representative studies of these types, see Cody, et al, 1992; Imai et al, 1986; National Research Council, 1989; Dockery et al, 1989; Pope, 1989; Ostro et al, 1991; Schwartz, 1989; Weiss and Wagener, 1990). In addition, the quality of the indoor environment is of particular importance, given the fact that many persons spend the majority of time inside (Spengler and Sexton, 1983). Also, the indoor environment may accumulate pollutants from the external environment, and may also retain pollutants released from natural sources (such as radon), from interior activities (such as smoking), and from products inside the home (such as formaldehyde from plywood composites and solvents from synthetic fabrics and carpets).

It may be argued that air pollution cannot be responsible for asthma, since air quality has been (purportedly) improving over the period of time in which asthma prevalence has increased. Despite improvements, over 150 million Americans still live in places where ozone levels exceed the National Ambient Air Quality standard (Cody et al, 1992).

In addition, there are several other possible explanations for this apparent persistence of air pollution-related health effects: first, air quality in the microenvironment may not have improved sufficiently to prevent sensitization or precipitation events; second, we may not have identified or sufficiently controlled the critical air

pollutant(s) related to asthma; third, we have not considered the overall quality of air as a totality of pollutant/particulate concentrations, a situation that is the result of regulatory processes that focus on one pollutant at a time; and fourth, the quality of the indoor environment may have deteriorated over this period as insulation and building practices decrease the rates of air exchange inside buildings.

These studies support the following recommendations:

## **1. Primary Prevention**

### **a. reconsideration of current air pollution standards**

EPA has recently considered these air pollutants for health and environmental effects, under the Clean Air Act. However, these considerations are deficient in two respects: first, as admitted by EPA, no comprehensive evaluation of current data on SO<sub>2</sub> has been undertaken; and second, no consideration has evaluated these pollutants together as they may affect lung function and risks of asthma. It may be the case that reducing one of these major pollutants without attending to the others will not bring exposures below the level associated with either sensitization or precipitation. **EPA should be required to undertake a state-of-the-art review of all current data on each pollutant, and to develop environmental policies that deal with the risks presented by all three pollutants experienced together in urban and other environments.**

### **b. increased attention to the quality of indoor air, and application of relevant regulatory authority to improve indoor air quality**

Many persons spend the majority of their day indoors, as pointed out by Stolwijk and others. For this reason, it is clear that the quality of the indoor environment is an important factor in asthma. Dust mites and other aeroallergens are well known triggers. The presence of other indoor air pollutants — including volatile organic compounds offgassing from synthetic products (such as carpets, laminates, paints, and composites), accumulation of radon, sidestream or passive smoke, and

other combustion products in well-insulated environments, and the entrapment of pollutants from the outdoor environment — have all been associated with “sick building syndrome” in occupational studies. Among the complaints of persons in such “sick buildings” are respiratory symptoms, including asthma-like breathing difficulties. **EPA must deal with these issues in an appropriate fashion, that is, through using the powers of TSCA to regulate product formulation and releases.**

## **2. Secondary Prevention Through the Establishment of Surveillance Systems**

Because of the difficulty in preventing asthma, attention is now being paid to developing strategies for asthmatics to monitor their own respiratory function in order to anticipate attacks so that ER treatment can be avoided (National Asthma Education Program, 1991; also Bailey, et al, 1992). In the Baltimore study, persons seen at the ER are being given flow meters and instructions on their use so that they can detect changes in lung function and alert health care providers or make necessary changes in self-medication as appropriate.

This provides an opportunity for persons with asthma to participate in an **interactive monitoring and surveillance systems linking air quality information (such as  $PM_{10}$ ,  $NO_x$ ,  $SO_2$ ,  $O_3$ , temperature and humidity) and asthma treatment centers, including emergency rooms.** Daily monitoring of air quality is done in many urban areas in the U.S. with histories of periodic decrements in air quality — these cities have in many cases developed an integrated “air quality index” that combines data on ozone, particulates,  $NO_x$  and  $SO_2$ . This information is usually publicized by the media and sometimes used by school authorities in deciding upon the appropriateness of children's outdoor recreation activities (Los Angeles).

There may be benefit in publicizing this information in connection with asthma education and outreach programs, similar to those being developed by the NAEP. That is, persons already identified as at risk for asthma through their utilization of

Little investment would be necessary to collect data on birth weight, since all hospital-based births have this information recorded. Birth weight appears to be a sensitive indicator of reproductive and developmental toxicity (Silbergeld and Tonat, in press), and state birth weight data have been used in studies of hazardous waste dumpsites (Love Canal - Vianna and Polin, 1983; Paigen and Goldman, 1987; see also, Stallones et al, 1992).

Somewhat more investment would be required to acquire data on asthma, but it is certainly feasible to develop systems to collect information on emergency room admissions and other health care provider contacts for asthma. As shown in the analyses of the NHANES II dataset (Weiss and Wagener, 1990; Schwartz, 1989), this information has great potential for correlating changes in environmental factors and disease incidence.

As noted above, we recommend that lead screening data be notifiable on standard forms to CDC. This information is being collected by some states at present, and a standardized computer based data management system has been developed by CDC (STELLAR).

#### **b. reinstate occupational disease and exposure registries**

Studies on the relationship between occupational exposures and disease have always played a critical role in improving our understanding of etiology. In part because workers are often exposed to higher amounts of toxic chemicals, and in part because exposures are relatively easier to assess, occupational epidemiology is a major contributor to environmental health knowledge. **Thus, as part of surveillance, the policies of the past 12 years, to discourage the collection and maintenance of occupational records relating to exposure and disease, should be promptly reversed.** Under the guise of "paperwork reduction", the Reagan-Bush OMB removed the requirements on industry to maintain such records for long periods of time.

Long-term data stability and access are essential to understanding exposure/disease associations, because many chemical-induced diseases are chronic and long in latency.

**c. expand the scope and nature of national health surveys**

The U.S. has a major instrument for the periodic assessment of population-based health and nutrition indicators, through the National Health and Nutrition Examination Survey (NHANES). This undertaking, designed by the National Center for Health Statistics, has provided us with much of our most valuable information on lead poisoning, asthma, and birth outcomes. The NHANES data have also forced us to face the inequities in the incidence of these diseases in our population (see, for instance, ATSDR 1988). Despite these successes, NHANES is underexploited as a source of information on exposures and disease related to the environment. Nor have we used NHANES to monitor our progress in reducing environmentally-induced disease, with the exception of the landmark studies on lead poisoning.

**The NHANES studies should be adequately funded, using the resources of Superfund through the statutory authority of the health provisions of SARA, to provide comprehensive information on the relationship between environment and disease; patterns of exposure to toxic chemicals in the US population; and associations between sources of exposure and adverse outcome.**

The experience of ATSDR in designing exposure registries should be incorporated into these NHANES studies, in order to increase their power and extend their relevance. Methods for sophisticated geographically-based studies have been developed and applied in environmental health (Stallones, et al, 1992).

**d. expand human tissue monitoring systems**

At present the US has only one national human tissue monitoring system, the National Human Adipose Tissue Survey (NHATS), which has been poorly funded and

implemented by EPA over the past decade. At present, EPA is attempting to sell off its tissue bank. NHATS is so limited that its data are of questionable value. However, the need for human tissue monitoring remains very great. Recent studies associating higher residues of pesticides in tissue from women with breast cancer (Wolff et al, 1993) underscore the importance of this information.

**A range of steps should be taken to improve our national human tissue monitoring resources. Coordination through regional medical centers will improve the rates of sampling and quality control; integration with NHANES design will ensure that data are interpretable and statistically valid; and improved communication among pathologists, epidemiologists, and analysts will ensure that appropriate samples are collected and stored.**

## **V. Research Needs**

Each of these areas requires further research. As noted by others, the health risks of women and children have been generally understudied by basic research agencies in the US, and the health problems encountered by disadvantaged women and their children are particularly neglected. Some of this research relates to health care delivery; this paper will focus upon research related to prevention through increasing our knowledge of disease-environment linkages. This study has demonstrated the complex interactions among low birth weight, asthma, and lead poisoning; further research is needed to explicate these interactions and to define more precisely the ways in which prevention can have multiplicative benefits.

### **1. lead poisoning**

While a large amount of research has been conducted on lead poisoning, particularly pediatric lead poisoning, over the past two decades, some major areas of uncertainty remain which impact upon our ability to deliver preventive health care

effectively and efficiently. First, much more information is needed on the exposures and effects of lead in adolescents, with particular reference to pregnant young women and their special risks. Second, the associations between lead exposure and low birth weight need further investigation. Third, the interactions between lead and nutrition are not founded upon much real data (Mahaffey, 1990), although considerable inferences are being drawn in the field of public health on the assumption that good nutrition is in some way preventive of lead poisoning.

Advances are needed in the rapid detection of blood lead levels, using finger-stick blood samples and rapid turnaround time, ideally applicable in a clinic setting.

## **2. low birth weight**

The distribution of low birth weight in U.S. populations needs study; selected populations have been studied, but we have no overall picture of the incidence of low birth weight among populations. An exemplary study of trends in birth weight has been done for New York City (Joyce, 1990) and similar research in other cities needs to be conducted. Particular attention should be paid to high risk populations, with respect to rates of adolescent pregnancy, undernutrition, special diets, and environmental quality. The interactions between environmental factors and other conditions, as pointed out by Walker et al (1992), needs intensive study, so that we can transcend the potentially unhelpful approaches of considering each factor in isolation by designs that “control” for real-world complexities.

Successful prevention of low birth weight has not been well studied in applied programs of health care delivery, that is, the extent to which improvements in access to prenatal care actually lower the risks of a low birth weight infant (Kleigman et al, 1992). The complexities of reproductive behavior in at-risk populations complicate these studies (Carnegie, 1992). Nevertheless, evaluation of WIC and other programs should be undertaken to study this outcome. If specific modifications are needed

in these programs in terms of risk evaluation or interventions, these should be instituted.

### **3. asthma**

Trends in asthma need to be assessed within specific populations. Methods to identify at risk populations, prior to onset, need to be identified. More research on asthma prevention, including research on the association between environmental (and other) factors and asthma, needs to be done, with particular but not exclusive emphasis on indoor air quality and the major ambient air pollutants (Buist and Vollmer, 1990). Innovations in delivering effective followup, using the growing home health care industry, should be tested and evaluated. More research on pharmacologic management is needed (NAEP, 1991).

Monitoring of asthma outbreaks should be correlated with air quality monitoring in order to provide interactive information to persons at risk and to coordinate health care delivery more efficiently. Treating asthma as a sentinel health effect can also help us to evaluate the adequacy of current air standards, and their implementation and enforcement.

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### Risk Assessment and Cost/Benefit Analysis: Strengths and Weaknesses

#### \* What is Risk Assessment and Cost/Benefit Analysis?

**Risk assessment** is a quantitative (i.e., numerical) or semi-quantitative compilation and evaluation of available data used to predict and estimate the adverse effects of a substance or activity on human health or the environment.

**Cost/Benefit analysis** is a comparison of the projected costs of a potential course of action to its projected benefits. In the regulatory context, the benefits part of a cost/benefit analysis is often derived through use of risk assessment, with the benefits equated to the risks prevented by the regulation. Cost/benefit analysis requires quantitative estimation of the magnitude of each cost and benefit.

#### \* What are the strengths of these tools?

They provide a framework for compiling, evaluating, and discussing complex information. They can provide a basis for setting priorities, allocating resources, and helping decision makers develop specific policies and standards. They can identify the most cost-effective ways of reaching particular goals.

#### \* What are the weaknesses of these tools?

**Risk assessments** are only as good as the information that is available to put into them. Unfortunately, for the vast majority of chemicals in widespread use in commerce, little or no information is available. Even for chemicals known to cause cancer, for example, it is almost never known whether they also impair the reproductive, immune, or neurologic systems of humans, or have effects on ecosystems. Only in a few instances is there relevant and reliable data from epidemiologic studies (i.e., those on groups of exposed humans). In most cases risk assessors utilize relevant data from well conducted animal studies, allowing society to act *before* substantial injury occurs in human populations. Methods to identify risks to ecosystems are even less well developed than those for health effects.

While substances like asbestos that cause rare "signature diseases" such as asbestosis can be identified through epidemiologic studies of exposed populations, substances with less distinctive effects require large studies (which are seldom conducted because of their expense) as well as clear ways to distinguish exposed and unexposed groups -- an extraordinarily difficult task for diseases with latency periods of 10, 20, 30, or more years.

In addition, there are substantial uncertainties over many aspects of risk assessment, even aside from key data gaps on specific substances. At present, scientists do not have enough information to resolve critical issues such as the basic mechanisms by which toxic substances cause cancer and other health effects. Nor do scientists know

with certainty how data from tests of laboratory animals should be interpreted with regard to human disease.

Many scientists believe that uncertainties should be resolved in favor of protecting health, but deciding whether to do so is not a wholly "scientific" determination. For example, if a substance causes cancer in female mice but not male rats, is it appropriate to try to reduce human exposure?

Finally, **ecological risk assessments** are even more limited by data gaps than risk assessments for human health. Scientists know so much less about most non-human animals, plants and systems that many parts of these risk assessments must be estimated, and/or "modeled" on computers, from very scant information. Ecologists cannot, for example, even begin to predict how single animal species in the Potomac River respond to increased use of road salt or backyard pesticides in the DC region. Predicting how the ecosystem of the River would respond to such changes requires fancy (and expensive) modeling and yields results that have a high degree of uncertainty.

**Cost/benefit analyses:** Because cost/benefit analysis uses the output of risk assessment, it incorporates the weaknesses of risk assessment. In addition, an individual cost/benefit analysis is limited by the quality of the risk assessment on which it is based. Even with good, data-rich risk assessments from which to compute benefits -- i.e., as the avoided risks -- many aspects of both costs and benefits are difficult to identify and calculate, and consequently are often disregarded or given only lip service. These problems become more severe as the amount of time and money spent on a cost/benefit analysis decreases.

Estimates of benefit often disregard socially critical factors. In particular, the benefits of avoiding health risks include far more than the medical bills and lost income associated with illness; they also include avoiding the loss of quality of life for those who fall ill, and associated impacts on their families, friends, and co-workers. The enormous and often protracted devastation of Alzheimer's disease, or incapacitating asthma in children, are examples of how non-fatal diseases can exact large and complex costs. For Alzheimer's disease, the total costs imposed on families and society are estimated to be four to ten times the cost associated with the individual case.

Measuring benefits in monetary terms is very difficult and expensive. Economists have not reached a consensus on the methods to be used or on the types of benefits for which monetary evaluation is credible. To the extent that it is usually more difficult to compute benefits than costs, cost/benefit analyses will be biased and the results will appear to support inaction. In addition, cost/benefit analyses sometimes apply discounting factors to both costs and benefits over time. However, for cancer, neuro-degenerative disease, and other illnesses with long latencies (i.e., lag time

between exposure and overt effect), these "discounts" can reduce the so-called present value of avoided risks to trivial amounts. This approach ignores the fact that for many of these diseases, disability persists for years before death.

In addition, cost analyses often neglect distributional issues: Who benefits from regulation versus maintenance of the status quo? Who pays? These issues often raise political and ethical issues far outside the realm of science or economics.

Cost/benefit analyses also fail to account for the fact that regulations themselves often prompt future technological developments that can reduce future compliance costs. For example, during debates on the Clean Air Act Amendments in 1990, some industry groups projected the cost of removing a ton of sulfur dioxide from utility emissions at \$1500, and EPA projected \$740/ton. But the actual price, as indicated by sales of tradeable emission credits, is currently \$140/ton -- a ten-fold decrease in less than five years. Absent the incentive provided by the new regulatory program, it is highly questionable whether these cheaper compliance strategies would have been developed. Initial estimates of cost can also be overstated as a result of unanticipated economies of scale, replacement of equipment or processes for unrelated reasons, and competition among industry.

While cost/benefit analysis can play a useful role in identifying most-bang-for-the-buck options available on a society-wide basis, most actual regulatory contexts offer little or no opportunity to shift funds from one goal to another. For example, even assuming that everyone agrees that it is socially preferable to spend \$1 billion to expand childhood immunization programs rather than clean up factory air emissions, a decision *not* to require factory owners to clean up their emissions provides no additional funding to immunization programs. Moreover, even universal immunization does nothing to reduce children's exposure to lead poisoning. Risks are not fungible; the task for policy makers is to ensure that *all* significant risks -- many of which interact -- are addressed.

## News Analysis

### Section IV

#### CALIFORNIA'S PROP 65: LESSONS FOR THE NATIONAL RISK DEBATE?

Don't be surprised if, within the context of the national debate about risk reform, you hear more and more about California's experience under Proposition 65, the state's "toxics law," which according to both environmentalists and industry demonstrates that companies have nothing to fear, despite initial panic about the potential economic impact of the law.

Congress and others involved in the national debate about risk reforms need to be aware of the eight-year track record of Proposition 65, which has "changed the whole dynamic of the toxics debate," according to Environmental Defense Fund Senior Attorney David Roe, an architect and long-time spokesman for the state's law.

During those eight years, says, Robert Reeves, director of industrial safety and health for the California Chamber of Commerce, implementation has proceeded "without much turmoil," and "companies are getting used to it." Though Reeves "would hate to see U.S. business under the same pressure as business in California," and considers the idea of applying Proposition 65 nationwide to be "frightening," he acknowledges that the law "has done some good," by raising awareness in companies about the toxic chemicals they use and "pushing technology" because companies seek alternative, safer chemicals for their products to escape the law's public warning provisions.

A 1992 report by a Proposition 65 Review Panel, issued under Republican Gov. Pete Wilson,

found that, "By federal standards, Proposition 65 has resulted in 100 years of progress in the areas of hazard identification, risk assessment, and exposure assessment." While no specific legislative proposals have yet been drafted, some environmentalists are discussing how the state law could be applied to federal clean water, hazardous waste, and other laws, Roe says.

Proposition 65 — The Safe Drinking Water and Toxic Enforcement Act of 1986 — became effective Jan. 1, 1987, amidst intense industry opposition and controversy, including an attempt by the food, cosmetics, over-the-counter drug, and other industries to persuade the Bush White House to federally preempt the state law for fear it would impose substantial economic costs outside California. Although the White House formed a Working Group on Federal Preemption to study the question, a Dec. 5, 1988 analysis by a related workgroup concluded that potential economic impacts on producers were vastly overstated, but suggested that federal agencies monitor implementation of the law to determine if future preemption might be needed.

Under the law, the governor must publish a list of chemicals known by the state to cause cancer or reproductive toxicity. That list must be updated each year. Businesses cannot "knowingly and intentionally" expose any individual to the chemicals, 12 months after they are listed, without first giving "clear and reasonable warning," although there are several exceptions. No warning is

required if exposures would result in a risk lower than "no significant risk," defined as "one excess case of cancer per 100,000 individuals exposed over a 70-year lifetime" for carcinogens, and as "less than one-thousandth of the no observable effect level" for reproductive toxicants. Other exceptions also apply that are not risk-related (e.g., businesses with fewer than 10 employees), and the law prohibits discharges of chemicals into state drinking water sources 20 months after listing.

The list now contains approximately 500 chemicals, including some chemicals with no commercial use (e.g., mustard gas) and 75 to 100 that are drugs whose potential health risks are told to users when they are prescribed (e.g., cancer therapy drugs). More than 250 numeric standards have been set for other commercially useful chemicals, and none of those standards have been challenged in court. By contrast, federal standards for toxic chemicals under the Clean Air Act failed to produce more than six numeric limits after 18 years, each one fought in court, and resulted in the 1990 amendments to the law whereby technological performance standards, not health effects, would be the basis for some 180 regulatory limits.

"Risk assessment has been the whipping boy, the process to blame for the lack of progress [in setting health-based standards], but the California experience shows it isn't so," according to EDF's Roe. "Risk assessment is not the problem, science is not the problem, lab space is not the problem — when the incentive is to get the homework done, it gets done ten times faster."

The unique incentive that Proposition 65 employs — making it in a company's interest to have numeric standards published so it can know whether it is meeting the "no significant risk" bright line — "favors promptness and certainty," unlike the traditional federal approach that favors "dragging out the rulemaking process," Roe explains. "The drafters recognized the unconscious disincentive in all the traditional federal laws and set out to reverse that and see what a difference it could make. It turned out to be astonishing," Roe says. The large number of standards

By federal standards, Proposition 65 has resulted in 100 years of progress in the areas of hazard identification, risk assessment, and exposure assessment.

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## News Analysis I

### Section IV

have been set with "less than one percent of EPA's annual toxics budget," by "raiding EPA's file cabinets" where assessment and analytic work had been "long since done," and by relying on industry to bring in the missing data once the incentive was to help regulators obtain information, Roe adds.

Enforceability is key to Proposition 65's success. Federal laws say "do all the homework first" before regulating, thereby inculcating an incentive to delay; Proposition 65 says that its warning provisions will be enforceable whether the government does the analytical work to decide if a risk is significant. "If you're an industry and exposing someone to a known carcinogen (a listed chemical), you want to know the size of the risk because you're legally at risk if you don't know," Roe explains. "You want to show you're within an acceptable limit," to define numerically what "no significant risk" means for specific chemicals. Proposition 65, which sets stiff penalties — \$2,500/day for each violation — and which allows "any person in the public interest" to bring suit after 60 days notice, applies to exposures "wherever, and however, they occur — walking down the street, in a factory, swimming in a ditch . . ." Roe says. Exposure is the issue.

"More than anything it is a right-to-know act," says Catherine Caraway, senior hazardous material specialist and lead person for Proposition 65 implementation within the California EPA's Office of Environmental Health Hazard Assessment. "The voters in '86 gave the state a clear message — they would no longer tolerate being exposed to carcinogens and reproductive toxicants without being informed." Once the law was in place, "It turned industry

around," Caraway says. Instead of "running away from information," industry "ran toward it," and actively sought clear guidance so businesses could determine if they were in compliance.

"It can be a difficulty with the law that everything is suspect," Caraway agrees, and has made it a priority to make sure companies go through the calculations to decide whether they must post warnings rather than simply posting a warning to ensure compliance, regardless of whether it is necessary. Caraway has concerns that too many postings could inure consumers to their significance and is working with companies to make sure they "don't just throw their hands up and wam, but think about whether they need to." The underlying impetus of the law is to encourage manufacturers to come up with safer alternatives if their products are found to pose more than "no significant risk."

One consultant familiar with the law says "whether it makes sense to take the 'guilty until proven innocent' concept from California to the rest of the country is a hard question," though it has a good enforcement mechanism and "gets you thinking about [pollution] prevention." For a long time there has been talk about bringing the concept to the national level, but Proposition 65 has the significant weakness that it ignores risk-benefit issues, focusing on individual emissions and exposures without getting at total, cumulative exposures, which is the only way to really assess risk, this source says. National debates about risk reform are concerned with avoiding expenditures on trivial risks, but the issue of how trivial a risk is and the benefits from reducing exposures is not part of the thought process under California's law, this source adds.

## Review

## Actual Causes of Death in the United States

J. Michael McGinnis, MD, MPP, William H. Foege, MD, MPH

**Objective.**—To identify and quantify the major external (nongenetic) factors that contribute to death in the United States.

**Data Sources.**—Articles published between 1977 and 1993 were identified through MEDLINE searches, reference citations, and expert consultation. Government reports and compilations of vital statistics and surveillance data were also obtained.

**Study Selection.**—Sources selected were those that were often cited and those that indicated a quantitative assessment of the relative contributions of various factors to mortality and morbidity.

**Data Extraction.**—Data used were those for which specific methodological assumptions were stated. A table quantifying the contributions of leading factors was constructed using actual counts, generally accepted estimates, and calculated estimates that were developed by summing various individual estimates and correcting to avoid double counting. For the factors of greatest complexity and uncertainty (diet and activity patterns and toxic agents), a conservative approach was taken by choosing the lower boundaries of the various estimates.

**Data Synthesis.**—The most prominent contributors to mortality in the United States in 1990 were tobacco (an estimated 400 000 deaths), diet and activity patterns (300 000), alcohol (100 000), microbial agents (90 000), toxic agents (60 000), firearms (35 000), sexual behavior (30 000), motor vehicles (25 000), and illicit use of drugs (20 000). Socioeconomic status and access to medical care are also important contributors, but difficult to quantify independent of the other factors cited. Because the studies reviewed used different approaches to derive estimates, the stated numbers should be viewed as first approximations.

**Conclusions.**—Approximately half of all deaths that occurred in 1990 could be attributed to the factors identified. Although no attempt was made to further quantify the impact of these factors on morbidity and quality of life, the public health burden they impose is considerable and offers guidance for shaping health policy priorities.

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IN 1990, approximately 2 148 000 US residents died. Certificates filed at the time of death indicate that their deaths were most commonly due to heart disease (720 000), cancer (505 000), cerebrovascular disease (144 000), accidents (92 000), chronic obstructive pulmonary disease (87 000), pneumonia and influenza (80 000), diabetes mellitus (48 000), suicide (31 000), chronic liver disease and cirrhosis (28 000), and human immunodeficiency virus (HIV) infection (25 000).<sup>1</sup> Often referenced as the 10 leading causes of death in the United States, they generally indicate the primary pathophysi-

ological conditions identified at the time of death, as opposed to their root causes. These conditions actually result from a combination of inborn (largely genetic) and external factors.

Because most diseases or injuries are multifactorial in nature, a key challenge is sorting out the relative contributions of the various factors. For heart disease, well-established external risk factors include tobacco use, elevated serum cholesterol levels, hypertension, obesity, and decreased physical activity; for various cancers, such risk factors include tobacco use, dietary patterns, certain infectious agents, and environmental or occupational exposure to carcinogenic agents. Even motor vehicle injuries can be associated with multiple factors, including alcohol use, failure to use passenger protection systems, poor roadway design, and inadequate

law enforcement. These factors may act independently of each other, the risks being additive according to the effect of each, or they may act synergistically, the interaction of factors presenting a greater total risk than the sum of their individual effects.

Available analyses of the roles of various external factors in these conditions suggest that the most prominent identifiable contributors to death among US residents are tobacco, diet and activity patterns, alcohol, microbial agents, toxic agents, firearms, sexual behavior, motor vehicles, and illicit use of drugs. When these contribute to deaths, those deaths are by definition premature and are often preceded by impaired quality of life. Although mortality is but one measure of the health status of a nation, the public health burden imposed by these contributors offers both a mandate and guidance for shaping health policy priorities.

## METHODS

This article summarizes published reports that attributed deaths to these contributors and presents a composite approximation of the totals reported for each (Table). Articles published between 1977 and 1993 were identified through MEDLINE searches, reference citations, and expert consultation. Government reports and compilations of vital statistics and surveillance data were also obtained. All relevant analyses were reviewed in full. Those selected for use in developing estimates were those most often cited and those for which the methodological assumptions could be identified.

The limitations in the data should be underscored both with respect to deficiencies in the primary databases (eg, the paucity of data on the role of drugs in motor vehicle fatalities or on long-term exposure levels of populations to various toxic agents) and to the disparate approaches used in the studies reviewed to arrive at estimates of the contribution of a factor to a particular health outcome. In some cases, assignments were attempted through simple tallies of available information about the presence or absence of a factor in association with a given outcome (eg, whether or not a

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driver in a motor vehicle fatality had a blood alcohol concentration above a certain level. In other cases, population-attributable risk calculations were used to arrive at estimates based on determinations of the relative risk for a particular health outcome of a population exposed to a specified health risk. Some of the studies presented meta-analyses of reports in the literature on a given topic. Estimates were often limited by the adequacy of information as to disease prevalence, risk factor prevalence, and the nature of the relationship to other contributing risk factors for the disease.

Despite their limitations, the results of such studies provide a sense of the relative impact of various factors on health in the United States. Derivation of the numbers presented in the Table is explained below in the discussion of each category. Where well-established methodologies have been developed for making the estimates, as with tobacco and alcohol, they have been used approximately as reported. For areas of greater uncertainty, such as diet and activity patterns and toxic agents, a sum of the lower boundaries of the estimates for various disease outcomes has been used. Although several of these factors are interrelated in their actions, care has been taken to avoid double counting. Given the fragility of the database involved and the fact that the studies cited use different approaches to derive estimates, these numbers should be viewed as first approximations.

## RESULTS

### Tobacco

Tobacco accounts for approximately 400 000 deaths each year among Americans. It contributes substantially to deaths from cancer (especially cancers of the lung, esophagus, oral cavity, pancreas, kidney, and bladder, and perhaps of other organs), cardiovascular disease (coronary artery disease, stroke, and high blood pressure), lung disease (chronic obstructive pulmonary disease and pneumonia), low birth weight and other problems of infancy, and burns.<sup>1</sup> In a major effort that drew on analyses that had been commissioned to assess the mortality, morbidity, and financial burden imposed by each of 15 priority health problems,<sup>2</sup> the Carter Center's *Closing the Gap* project attributed 17% (328 000) of all deaths in 1980 and 13% of all potential years of life lost from death before 65 years of age to tobacco.<sup>3</sup> Other estimates have placed tobacco's contribution in the range of 11% to 30% of cancer deaths,<sup>1,4-6</sup> 17% to 30% of cardiovascular deaths,<sup>1,8-14</sup> 30% of lung disease deaths,<sup>1,12</sup> 24% of pneumonia and influenza deaths,<sup>11</sup> 10% of infant deaths,<sup>17,18</sup>

and 20% to 30% of low-birth-weight infants.<sup>1,20</sup> Approximately 3000 lung cancer deaths annually among nonsmokers have been attributed to environmental tobacco smoke.<sup>21</sup> The sum of the lower and upper boundaries, respectively, for these estimates would yield an approximate range of 257 000 to 458 000 tobacco-attributable deaths in 1990. Using a specially developed software package,<sup>22</sup> the Centers for Disease Control and Prevention (CDC) estimated that 418 690 deaths were caused by tobacco in 1990, including approximately 30% of all cancer deaths and 21% of cardiovascular disease deaths.<sup>17,23</sup> The CDC estimates have been widely accepted and provide the basis for the 400 000 figure included in the Table.

### Diet and Activity Patterns

Dietary factors and activity patterns that are too sedentary are together accountable for at least 300 000 deaths each year. Dietary factors have been associated with cardiovascular diseases (coronary artery disease, stroke, and high blood pressure), cancers (colon, breast, and prostate), and diabetes mellitus.<sup>24</sup> Physical inactivity has been associated with an increased risk of death for heart disease<sup>25,27</sup> and colon cancer.<sup>26,28</sup> The interdependence of dietary factors and activity patterns as risk factors for certain diseases is illustrated by the case of obesity, which is associated with increased risk for cardiovascular disease, certain cancers, and diabetes, and is clearly related to the balance between calories consumed and calories expended through metabolic and physical activity. Similarly, high blood pressure, a major risk for stroke, can be affected by dietary sodium, obesity, and sedentary lifestyle. The Carter Center review of deaths in 1980 attributed 290 000 deaths to overnutrition and another 297 000 to high blood pressure.<sup>2</sup> Sedentary lifestyles have been linked to 23% of deaths from the leading chronic diseases.<sup>29</sup> An assessment of the decline in coronary artery disease mortality from 1968 to 1976 credits reductions in serum cholesterol levels with about a third of the improvement.<sup>30</sup> Some studies credit changes in sodium consumption with the potential to lower death rates for coronary heart disease by 16% to 30% and stroke death rates 25% to 39%.<sup>31,32</sup> Half of all type II diabetes (non-insulin-dependent diabetes mellitus) is estimated to be preventable by obesity control.<sup>33</sup> A 50% reduction in consumption of animal fats might result in a proportionate reduction in risk for colon cancer.<sup>34</sup> In the most extensive analysis to date of studies on risk factors for cancer, Doll and Peto established 35% as their best estimate for the proportion of all cancer deaths attributable to diet.<sup>3,35</sup>

Actual Causes of Death in the United States in 1980

Cause	Deaths	
	Estimated No. <sup>a</sup>	Percentage of Total Deaths
Tobacco	400 000	19
Chronicity patterns	300 000	15
Alcohol	100 000	5
Motor vehicle	50 000	2
Toxic agents	60 000	3
Fragility	35 000	2
Sexual behavior	30 000	1
Minor venoms	25 000	1
Use of drugs	25 000	<1
Total	1 085 000	50

<sup>a</sup>Composite approximation drawn from studies that use different approaches to derive estimates, ranging from actual counts (eg, injuries) to population attributable risk calculations (eg, 125 cases). Numbers over 100 000 rounded to the nearest 100 000; over 50 000, rounded to the nearest 10 000; below 50 000, rounded to the nearest 5000.

Other studies have associated dietary factors or sedentary lifestyles with 22% to 30% of cardiovascular deaths,<sup>1,36,37</sup> 20% to 60% of fatal cancers,<sup>1,38,39</sup> and 50% to 80% of diabetes mellitus cases.<sup>1,3,33</sup> Including 80% of diabetes deaths.<sup>1,33</sup> If the boundaries of these various estimates were summed, they would yield a range of approximately 309 000 to 582 000 deaths in 1990 related to diet and activity patterns. Because of the complexity of the issues and the difficulty of the analyses relating diet and activity patterns to disease outcomes, the lower bound is used as the basis for the 300 000 deaths figure presented in the Table.

### Alcohol

Misuse of alcohol accounts for approximately 100 000 deaths each year, but the related health, social, and economic consequences of alcohol extend far beyond the mortality tables. An estimated 18 million US residents suffer from alcohol dependence,<sup>2,40</sup> and some 76 million are affected by alcohol abuse at some time.<sup>41</sup> Estimates of alcohol's death toll range from 3% to 10% of deaths.<sup>42,43</sup> Various estimates have placed alcohol's contribution in the range of 60% to 90% of cirrhotic deaths,<sup>44</sup> 40% to 50% of motor vehicle fatalities,<sup>1,38,45</sup> 16% to 67% of home injuries, drownings, fire fatalities, and job injuries,<sup>1,38,46</sup> and 3% to 5% of cancer deaths.<sup>4,17</sup> The Carter Center project estimated that 6% of deaths and 15% of potential years of life lost before age 65 were attributable to alcohol use.<sup>4</sup> Summing the boundaries of these estimates yields an approximate range of 57 000 to 107 000 alcohol-related deaths in 1990. The CDC used clinical case studies and analytic epidemiologic studies to determine alcohol-attributable fractions of various diagnoses and concluded "a total of 105 095 deaths were caused by alcohol in 1987, including approximately 30 000 deaths from unintentional injuries, 19 600 from digestive diseases in-

cluding liver cirrhosis, 17 700 from intentional injuries, and 18 000 from cancers.<sup>40</sup> Because the CDC estimate is the one most often reported, it has been applied to 1990 death rates and serves as the basis for the 100 000 alcohol-related deaths included in the Table.

#### Microbial Agents

Infectious agents—apart from those counted elsewhere with causes of the human immunodeficiency virus (HIV) infection or consequent to use of tobacco, alcohol, or drugs—currently account for approximately 90 000 deaths per year. Infections were once the leading killer in the United States, and they are still a prominent threat, especially to persons with other health impairments. Infectious agents also exert great influence on society through an estimated 740 million nonfatal illnesses caused by symptomatic infections that occur annually among Americans.<sup>41</sup>

Although immunizations and infection control measures may already prevent as many as 135 million infections and 63 000 deaths annually in the United States,<sup>42</sup> a substantial fraction of the infections and deaths that do occur are also preventable. The major contributors to death from infectious agents are pneumococcal pneumonia, nosocomial infections (in both acute and chronic care facilities), legionellosis, *Staphylococcus aureus* infection, hepatitis, and group A streptococcal infections. Vital statistics reports for 1990 indicated the number of deaths from infectious and parasitic diseases to be 55 612, plus another 79 513 from pneumonia and influenza and 1289 from meningitis and encephalitis.<sup>43</sup> The Carter Center study of deaths occurring in 1985 estimated that nearly 200 000 deaths could be attributed to infections, of which 13% were potentially preventable with current vaccines.<sup>44</sup> Hepatitis B infection is a good example. Approximately 5000 deaths in 1988 resulted from hepatitis B infection, including about 25% of all deaths from primary liver cancer, although a vaccine has been available since 1982.<sup>45-48</sup> Tuberculosis, which ranked second as a cause of death in 1900, accounted for 1810 of the infectious disease deaths in 1990,<sup>4</sup> and with the spread of antibiotic-resistant strains, tuberculosis gives evidence of increasing in this decade.<sup>49</sup>

The difficulty of assigning responsibility for infectious disease deaths is illustrated by the fact that, while the number of classic bacterial pneumonia deaths increased about 10% from 1980 to 1990, those classified as "other" and "unspecified organism" increased by more than 50% and now account for approximately 90% of all pneumonia deaths.<sup>4</sup> A substantial part of the growth in these cat-

egories reflects the impact of the HIV epidemic, but most of those deaths are counted in this review under deaths attributable to unprotected intercourse or drug use.<sup>50</sup> Moreover, many deaths from pneumonia occur among cancer, heart, lung, and liver disease patients and are therefore traceable to other causes such as tobacco, diet, and alcohol (eg, the 24% and 4% of pneumonia and influenza deaths ascribed to tobacco<sup>51</sup> and alcohol,<sup>48</sup> respectively). Other pneumonia deaths that may also be related to more proximal causes, but which are as yet unassigned, are counted here as general infectious disease deaths. Hence, the 90 000 deaths included here for microbial agents represent the sum of 1990 deaths from key International Classification of Diseases codes 001 through 139 (infectious and parasitic diseases), 320 through 323 (meningitis and encephalitis), and 480 through 482 (pneumonia and influenza), and not including those from codes 042 through 044 (HIV infection) and those otherwise estimated to be attributable to tobacco use, alcohol use, sexual behavior, and illicit use of drugs.

#### Toxic Agents

Estimates of the deaths attributable to toxic agents vary widely, and because measurement techniques and the recognition of health effects are still evolving, the number of 60 000 per year included in the Table may be the most uncertain of the figures indicated for the various causes.

Toxic agents may pose a threat to human health as occupational hazards, environmental pollutants, contaminants of food and water supplies, and components of commercial products. They can contribute to conditions that are potentially lethal, including cancer and other diseases of the heart, lungs, liver, kidneys, bladder, and neurological system. Estimates of the total cancer deaths caused each year by synthetic chemicals in the environment or occupational settings range upward from about 30 000,<sup>52</sup> including an estimated 9000 from asbestos exposure.<sup>53</sup> Occupational exposures alone have been estimated to cause 1% to 3% of all cardiovascular, chronic respiratory, renal, and neurological disease deaths, as well as all pneumoconioses.<sup>54</sup> In addition, occupational exposures have been linked with about 4% to 10% of all cancer deaths,<sup>55,56</sup> and pollutants with approximately another 2% of all cancer deaths.<sup>4</sup> Although evidence is generally unavailable for the long-term effects of ambient pollutants on cardiovascular or pulmonary death rates,<sup>57</sup> significant elevations of respirable pollutants such as particulates, sulfur dioxide, and carbon monoxide have been associated with transient increases in daily mortality

rates of 4% to 16%.<sup>58-61</sup>

Indoor air may present a greater burden of pollutants than outdoor air.<sup>62,63</sup> Environmental tobacco smoke is an established carcinogen,<sup>64</sup> and estimates of radon's contribution to lung cancer deaths range from about 7000 deaths per year to nearly 24 000 deaths per year.<sup>65,66</sup> In all, geophysical factors such as background ionizing radiation and ultraviolet light may be accountable for some 3% of cancer deaths.<sup>4</sup>

The sum of the boundaries for these estimates approximates a range of 57 000 to 108 000 deaths in 1990 related to toxic agent exposure. The nonfatal effects of toxic exposures in the environment may present even more widespread consequences. For example, fatal lead poisoning is rare, but the toll from high blood lead levels may be lifelong learning impairment for some of the more than 230 000 children now exposed to blood lead levels greater than 120  $\mu\text{mol/L}$  (25  $\mu\text{g/dL}$ ).<sup>67</sup> Urgent questions are also raised about environmental changes such as atmospheric warming and ozone depletion. Given the uncertainties related to toxic environmental exposures and the ubiquitous character of their impact, an even more compelling challenge than identification of their current mortality burden is clarification of the nature of the issues, the exposure trends, and their likely long-term consequences. The figure of 60 000 presented in the Table for estimated total deaths from toxic agents represents the sum of the lower boundaries of various estimates of the contribution of toxic agents to deaths from cancers and (for occupational exposures only) other diseases of the lung, cardiovascular, renal, and neurological systems.

#### Firearms

Firearms caused more than 36 000 deaths among Americans in 1990, including about 18 000 homicides, 19 000 suicides, and 1400 unintentional deaths.<sup>4</sup> The number of deaths caused by firearms is now higher than those caused by motor vehicle crashes in five states and the District of Columbia (unpublished data, National Center for Health Statistics, September 8, 1993). Comparison data indicate that firearm-related homicide rates for young males in the United States are 12 to 273 times the rates in other industrialized nations, whereas non-firearm-related homicide rates are 1.4 to 9.2 times greater than those elsewhere.<sup>68</sup> For example, in 1986 there were 1043 firearm-related homicides among US males aged 15 to 19 years, compared with six such deaths in Canada and two in Japan.<sup>69</sup> Firearm-related deaths now comprise 11% of all childhood deaths and 17% for those

aged 15 to 19 years, including 41% of deaths among black males of this age.<sup>44</sup> Firearm-related suicides among black teenage males aged 15 to 19 years doubled from 1982 to 1987, and although the rate for white males the same age did not change substantially during this period, it was nearly twice as high.<sup>44</sup> The risk of suicide among adolescents has been found to be nearly three times greater in homes where a gun is kept.<sup>44,45</sup> Moreover, guns kept in homes as protection have been found to be several times more likely to kill a family member than an intruder.<sup>46</sup> The prominent, detrimental effect of firearms on overall death rates in the United States is unique in comparison with other countries.<sup>47</sup>

### Sexual Behavior

Unprotected sexual intercourse was accountable for approximately 30 000 deaths in 1990. Sexual behavior is associated with substantially increased risk for preventable disease and disability and is the source of some of today's most prominent social challenges. Each year, 12 million persons (two thirds of whom are under 25 years of age) are newly infected with a sexually transmitted disease.<sup>48</sup> An estimated 56% of all pregnancies among US women are unintended,<sup>49</sup> including most of the 1 million that occur among US teenagers each year.<sup>48</sup> One of the most rapidly increasing causes of serious illness is hepatitis B infection, of which about a third is estimated to be sexually transmitted.<sup>50</sup> Among women, pelvic inflammatory disease is a severe complication of lower genital tract infections such as gonorrhea and chlamydia. Each year pelvic inflammatory disease affects an estimated 1 million US women,<sup>51</sup> of whom perhaps as many as 150 000 become sterile as a result.<sup>52</sup>

The 30 000 deaths in 1990 attributed in the Table to unprotected sexual intercourse include approximately 5000 from excess infant mortality rates among those whose pregnancies were unintended,<sup>53</sup> 4000 from cervical cancer,<sup>1,54</sup> 1800 from sexually acquired hepatitis B infection,<sup>48</sup> and 21 000 from sexually acquired HIV infection.<sup>55</sup> As indicated by the nearly 20% increase over deaths in the previous year from sexually acquired HIV infection, unprotected intercourse now represents one of the most rapidly increasing causes of death in the country.

### Motor Vehicles

Motor vehicle injuries to passengers and pedestrians caused about 47 000 deaths in 1990.<sup>1</sup> Nearly 40% of all deaths among those aged 15 to 24 years were caused by motor vehicles.<sup>56</sup> The chances of surviving a serious motor vehicle crash

are increased severalfold if an occupant is protected. Lap and shoulder belts have been shown to reduce the risk of death by about 45% to 65%, and of serious injury by about 40% to 56%.<sup>57</sup> Airbags have been shown to yield a 30% reduction in fatalities and a 35% reduction in serious injury in frontal crashes.<sup>58</sup> Child passenger restraints can reduce fatalities by 50% to 90%.<sup>59</sup> Use of motorcycle helmets can reduce fatalities by 80% and serious head injuries by 75%.<sup>60</sup> The estimate of 25 000 deaths attributed in the Table to motor vehicles does not include those already recorded as relating to alcohol or drug use.<sup>12,61,62</sup>

### Illicit Use of Drugs

Approximately 20 000 deaths were caused in 1990 by illicit use of drugs. It is estimated that some 3 million people in the United States have serious drug problems.<sup>7</sup> Illicit use of drugs contributes to infant deaths and to deaths reported for such causes as overdose, suicide, homicide, motor vehicle injury, HIV infection, pneumonia, hepatitis, and endocarditis. In 1990, approximately 9000 deaths nationwide were attributed to illicit use of drugs (both legal and illegal) by vital statistics reports. This figure, however, does not include those indirectly related, such as deaths from accidents, homicides, infections with HIV, and hepatitis.<sup>4</sup> In 1980, approximately 9000 HIV deaths resulted from intravenous drug use (20% more than 1989),<sup>70</sup> as did at least another 1300 hepatitis B-related deaths.<sup>48,63</sup> In addition, the National Highway Traffic Safety Administration estimated in 1988 that other drugs, often in association with alcohol, may be a factor in 10% to 22% of highway crashes.<sup>64</sup> The problem of accurately identifying drug-related deaths is illustrated by a study of the Drug Abuse Warning Network (DAWN) data and the national vital statistics reports of cocaine-related deaths in 25 metropolitan areas, which found that about 75% more cocaine-related deaths were reported by DAWN than by the vital statistics system from 1983 to 1988.<sup>65,66</sup> A study of deaths from 1978 to 1988 in New York City identified 1091 deaths in 1986 as "narcotics-related," only 247 of which had been specifically attributed by vital statistics to drugs. Some 241 deaths were attributed to unspecified pneumonia, 172 to liver disease, and 113 to endocarditis.<sup>66</sup> The findings of that study suggest that there may be a substantial undercount of the role of intravenous drug abuse relative to these and other causes of death. Although local vital statistics reports indicated an increase of 50% in drug-related deaths from 1978 to 1986, the study cited found a much more rapid increase of more than 400% for the same period.<sup>66</sup> Further com-

plexing this analysis is the fact that the use of illegal drugs by pregnant women increases the risk for a poor pregnancy outcome, including infant death. The National Commission to Prevent Infant Mortality reported in 1992 that such drugs may be used by as many as one in five pregnant women nationwide.<sup>67</sup> The 3000 deaths attributed in the Table to drug use represents deaths reported to the vital statistics system as drug-related, as well as those from drug-related HIV infection, automobile injuries, and hepatitis infections. It, too, is expected to increase substantially in future years as a result of HIV deaths associated with intravenous drug use.

### Other Factors

Lack of access to a reliable source of primary care is also associated with an increased risk of death from a variety of causes, although quantifying the impact is complicated by the challenges of appropriately characterizing the various elements of access and distinguishing their effects on a given health outcome from other confounding variables. Comparisons of the health status profiles of various developed countries suggest that residents of countries that provide relatively greater access to a full range of primary care services generally fare better than residents of countries with poorer access.<sup>68</sup> The Carter Center project estimated that gaps in primary care indicated by lack of access to standard primary care, screening, and preventive interventions, accounted for 7% of premature deaths and 15% of potential years of life lost before age 65 in 1980, of which substantial portions were due to infant deaths.<sup>69</sup> Limitations on access and use of appropriate primary care services require very close scrutiny as important determinants of health status for many Americans and present an obvious target of opportunity for a nation with 15% of the population currently uninsured.<sup>70</sup>

Poverty too has its own direct effect on mortality rates, although it is difficult to separate the effect of lack of access to primary care from that of social and economic status. In the United Kingdom, which guarantees universal access to services, a substantial differential remains in health status outcomes by social class despite improved access,<sup>71,72</sup> and overall scores in health status indicators are somewhat lower than those for other more socially homogeneous Western European countries.<sup>73</sup> Similarly, reports indicate that poor Canadians have a projected 11 fewer years of disability-free life than their more affluent counterparts despite guaranteed access to medical care.<sup>74</sup> Several studies that have controlled for other risk factors have shown

that populations characterized by low educational or income status experience poorer health prospects.<sup>8,9,14</sup> People who are poor have higher mortality rates for heart disease, diabetes mellitus, high blood pressure, lung cancer, neural tube defects, injuries, and low birth weight, as well as lower survival rates from breast cancer and heart attacks.<sup>8,9,15</sup> For example, a study of the relative contribution of various risk factors and income levels to mortality among blacks estimated that 38% of excess mortality could be accounted for by family income and 31% by six risk factors (smoking status, blood pressure, cholesterol level, body mass index, alcohol use, and diabetes), with 31% remaining unexplained.<sup>16</sup> Efforts to improve health must take into account the special challenges to those who are poor.

## COMMENT AND CONCLUSIONS

Approximately half of all deaths that occurred among US residents in 1990 could be attributed to the factors identified. Despite their approximate nature, the estimates presented here hold implications for program priorities. At the most basic level, they compel examination of the way the United States tracks its health status. Clearly, there is a need to improve the assessment of the contributory effects of etiologic factors on deaths among US residents and to clarify the role of factors such as poverty and restricted access to health services. There is also a need to look more specifically at how these factors affect the 50% of all deaths that occur before age 75. Moreover, there is a need to assess how they affect our measures on the increasingly important dimensions of morbidity and quality of life. Our national efficiency in changing the health profile is dependent on our ability to identify and monitor trends for the major factors that give direct shape to that profile.

The most important implications of this assessment of the actual causes of death in the United States are found in the way the nation allocates its social resources and shapes its program emphases. In 1993, health care costs in the United States are expected to reach approximately \$900 billion,<sup>17</sup> an average of more than \$14 000 annually for each family of four, if equally allocated across the population. The preponderance of this expenditure will be devoted to treatment of conditions ultimately recorded on death certificates as the nation's leading killers. Only a small fraction will go to the control of many of the factors that the Table indicates imposed a substantial public health burden. The national investment in prevention is estimated

at less than 5% of the total annual health care cost.<sup>18</sup>

There can be no illusions about the difficulty of the challenges in changing the impact these factors have on health status. Of those identified here, the three leading causes of death—tobacco, diet and activity patterns, and alcohol—are all rooted in behavioral choices. Behavioral change is motivated not by knowledge alone, but also by a supportive social environment and the availability of facilitative services. The most rapidly increasing among these causes of death—sexual behavior and illicit use of drugs—take place behind closed doors and are difficult to confront directly even in a putatively open society. Several of the causes of death, such as firearms, are the focal point of powerful lobbies that impede constructive exploration of the full range of social options.

Nonetheless, the central public health focus for each of these factors must be the possibility for improvement. Change can occur. In recent years, trends have been salutary on several dimensions, eg, reductions in tobacco use, saturated fat consumption, and motor vehicle fatalities. The discouraging trends with respect to the effects of sexual behavior, firearms, and illicit use of drugs need not be inexorable. If the nation is to achieve its full potential for better health, public policy must focus directly and actively on those factors that represent the root determinants of death and disability.

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Mr. BROWN. Thirdly, let me see if I can try and categorize the dynamics of what's been happening on risk assessment. As several of you may have pointed out, including Dr. Ritter, this is not a new subject for this committee. We've been exploring it for 15 years. And we have not had much luck in getting agreement on it, because it's a rapidly evolving field, with many complexities and difficulties. But it seems to me that we're making some progress here.

Successive Presidents, beginning with President Reagan, have issued Executive Orders on risk assessment, and each succeeding President has replaced it with what he thought was a better Executive Order on risk assessment. And the total process has aimed at reducing some of the evils of overbureaucratic regulation and undue hardship within the regulated community while maintaining the benefits of additional public health and safety that stems from it.

That process has been going on, maybe a little jerky in places, but it's still been going on. And today we have a situation where we got born again bureaucrats who all swear that they've now got religion and they're not going to do heavy-handed regulation, everybody in Congress is a "me too but"; now we support the principle but we think we can do it better. And it seems that our main problem right now might be in our rush to judgment, we're going to overlegislate in a situation which is already moving in the right direction.

May I ask you to comment, if I am completely off track on this I'd like to know about it, but would any of you disagree radically with that?

Mr. AUCHTER. Mr. Brown, if I might, the—I believe, as a former risk manager, that the fundamental necessity is for a congressional expression of intent. That's the—that's what's been lacking. That's why we've had the herky-jerky, some legislation requires some things, some require the other. I think Congress has to speak to this issue. I think that's important.

Mr. BROWN. Well, may I just respond to what you said? Mr. Auchter, you made a couple of references to the Johnston amendment, which was overwhelmingly adopted in the Senate, and to the \$50,000—50,000 annual traffic deaths. The 50,000, I don't think, is quite right. It was 50,000 15 years ago. It's down to about 25 or 30,000 at the present time. And I'm using that—I make that point to illustrate that that's due to regulation of automobile safety and it shows a continuous down trend because of a continuous effective regulation.

You also, in mentioning the Johnston amendment, the Johnston amendment merely codifies the language in the Clinton Executive Order. And that again is an indication that we're gradually moving in the right direction, where the Senator adopts the President's language, and then tries to say the Senate or the Congress is adding additional weight to this language. I don't think he changed it in any essential respect. Yes.

Mr. PORTNEY. If I could briefly respond, I think I agree with Thorne Auchter that we do need some kind of congressional expression of concern about this. And I think the best example I can give goes back to the time when Bill Ruckelshaus was administrator of EPA, the second time, between 1983 and 1985. He was under direc-

tion from a Presidential Executive Order, that was Executive Order 12291, to do a benefit cost analysis that—in support of the revision of the national ambient air quality standard for particulates. When he was about to promulgate the standard, he said, wait, we don't have a benefit cost analysis, you have to go do one. His staff hustled out and did diligent work and prepared a benefit cost analysis. And then to please him, they brought it to him and he said, "Oh, my God, don't show it to me, because I can't look at the costs associated with the alternatives that I'm considering here". And so we need not just a congressional statute pointing out the importance of doing this kind of analysis, that goes back to my earlier point that we need to address the individual statutes right now that prohibit costs from even being one factor that's taken into account.

Mr. BROWN. If I may just comment in conclusion here, I don't disagree with this comment. I do think we need a statement of congressional opinion, and we've been trying to get that. What I would like to suggest here, that there could be benefits both to the process and to the Republican platform position, which is very solid, that we've got to reduce the adverse impacts of government, if we could get together on the language of a bill which will not do damage to the progress being made, and which the Republicans can take credit for in establishing a new high level of congressional interest in this.

The CHAIRMAN. Dr. Yosie.

Mr. YOSIE. Just very briefly, I would as a former official of EPA for about 10 years, I would acknowledge there has been a lot of progress in terms of improving risk assessment, developing guidelines. Incrementally, there has been more scientific information available, and risk procedures have improved. But I think overshadowing that, in my judgment, is that the regulatory system that has been in existence for environmental policy since the 1970s, I think is in a fairly profound state of crisis right now. And I think what is needed is a new set of ground rules, and a new set of criteria by which the country can regain his confidence in the decision-making process.

One cannot make environmental policy these days without affecting innovation, without making trade policy, without affecting economic development. And I think some greater, more clear statement from the Congress, would set the House in order, in order to achieve what we all want to achieve, which is environmental quality in the most cost-effective manner possible.

Mr. RITTER. I just have a brief comment. It's been mentioned many times today that this bill could constitute overkill. CBO has analyzed the costs of this bill, Title III, as something like \$20 million. Think of the regulatory costs that stack up against that \$20 million. I mentioned asbestos and in the schools is \$10 billion, Clean Air Act, up to \$50 billion.

And the other thing I wanted to say, was this bill is prospective. The potential impact of this bill is not that great. Not yet, anyway. I mean, it could be when reauthorizations come up, or if something—but right now, it will cover fairly limited amount of subjects.

The CHAIRMAN. Thank you very much. Mr. McHale.

Mr. McHALE. Thank you, Mr. Chairman. Mr. Chairman, I have just a couple of questions for Mr. McGarity, Professor McGarity, and also for my friend and your former colleague, Dr. Ritter, beginning with Mr. McGarity.

A long time ago, before I came to this place, I used to practice environmental law and had some contact with the EIS requirements under NEPA. During your earlier testimony, you made reference to analogous litigation that might arise under this statute were it to be enacted, pursuant to which challenges could be brought in the courts concerning the adequacy, perhaps even the timing of risk analysis and assessment, as well as cost-benefit analysis.

Could you expand on that a little bit? What—specifically in terms of standing, the scope of litigation, potential delays that might be involved. And I don't ask this inviting a particular answer, truly it's an open-ended question. Are we looking at the prospect of litigation under this Title III of H.R. 9 that would, in fact, parallel existing remedies available in the Federal courts under the EIS section of NEPA?

Mr. MCGARITY. Yeah, I think—excuse me. I think of the answer is clearly yes. In fact, there will be more NEPA legislation because of this. Because NEPA environmental impact statements have risk assessments in them. Those risk assessments will be subject to these requirements, and so we'll see that claim made in existing NEPA adequacy litigation.

But the cost-benefit section, because it has its clear threshold that says for major rules you shall engage in this cost-benefit assessment, is a clear signal to any litigant out there that if they don't do the cost-benefit analysis, I can sue. And that's your whole 10 years of NEPA threshold litigation that you saw in the early 1970s, repeated now with respect to cost-benefit analysis in regulatory agency decisions.

The other analog of NEPA litigation is the adequacy litigation, that still goes on. You don't see much threshold litigation any more, because the agencies have evolved various environmental assessments, FONISs, findings of no significant impact and that sort of thing, which I truly would predict would come out of this as well. But the adequacy litigation would likewise happen here, and that would be directed both to the risk assessment and the cost-benefit analysis.

Mr. McHALE. I have a concern about that. It reminds me of the old statement, be careful what you hope for, you may get it. Those who are anxious, and I am truly sympathetic to the implementation of effective cost-benefit analysis and effective risk assessment, but I was alarmed to hear your description earlier and your amplification of it just a few moments ago that we're looking at the potential for litigation programs as great or even greater than that which has occurred under NEPA.

Under NEPA, it took years to establish a whole body of case law, to give full meaning to the adequacy of an environmental impact statement. And I am concerned that at a minimum those who vigorously advocate risk assessment understand the potential risk and costs associated with subsequent litigation.

Mr. MCGARITY. I share that concern.

Mr. MCHALE. Would you have any kind of suggestion that you might bring forward that would reasonably limit that potential for litigation exposure?

Mr. MCGARITY. I mentioned in my testimony a limitation on judicial review that you could write into the statute itself, except insofar as the review occurs at the substantive, as part of substantive review of the record support for the rule. I think that's entirely appropriate, to talk about the problems that you might see in a risk assessment, when you're talking about the problems that you see with the rule, at the end of the line.

And so I think that's how you might do it, is craft some sort of provision. And you might even specifically address the timing question and simply say timing of judicial review won't be appropriate until the final rule is promulgated, something of that sort.

Mr. MCHALE. Thank you.

Don, my next question is for you. If I could ask you to relate in your professional opinion the content of Title III H.R. 9 and the specific subject on which both you and I have a strong interest of Brownfields reclamation.

We had a hearing before one of the subcommittees of this committee in the last session on Brownfields reclamation. Gus Moffett from Bethlehem Steel came down. We specifically talked about the need that you and I are familiar with at Bethlehem Steel, but truly that it exists in virtually every congressional district across the country, to clean up older industrial sites, to do so in a scientifically valid way with appropriate risk assessment, and to convert those older properties to new and commercially viable uses.

What relationship, if any, do you see between Title III and that ongoing challenge of reclamation?

Mr. RITTER. It's a really good question, Mr. McHale. I want to mention that I did not plant this question, but it is a very good question. It will really assist in the—in speeding up the reclamation of these old industrial sites. It's a part of a larger picture.

The question is how clean is clean enough. And that involves other dimensions than just a scientific risk assessment. It involves legal considerations that might arise in Superfund. I believe this bill will have a major impact on the Superfund legislation as it arises in the course of this year. But also what it does, it gives some kind of structure to State and local government to handle some of these things.

This issue that you brought up is so broad, it's so nationalized everywhere, particularly in the older States like Pennsylvania, that to expect the Federal Government to do this out of a command and control model would be unrealistic and put a tremendous burden on the system. So this will give guidelines to mayors, to city councilmen, to county executives, to State DEP, DEQ, DER type departments, and because right now they have to somehow come out of this, come out of thin air with their definition of what the appropriate risk assessment is. It will give guideline.

Mr. MCHALE. I thank you. My time is expired. I would simply note in closing that following up on our friend and former colleague, Tom Ridge, who is now the Governor, on this subject utilizing these principles, I plan to introduce a comprehensive bill. Thank you, Mr. Chairman.

Mr. RITTER. We're working with our former colleague as well.

The CHAIRMAN. I thank you. If you have a follow-up, you were good enough to give us your time in the first round. If you have a follow-up, and I saw I think Mr. Burke might want to respond to you here.

Mr. MCHALE. Mr. Burke, would if you would. Thank you, Mr. Chairman. I appreciate it.

Mr. BURKE. As a former State regulator, I just feel like I should respond to this.

This bill, I wish it did, but this bill does not answer the question how clean is clean. Nor does it address the issues around, unfortunately, some of these industrial sites, so that people who are very concerned about their long-term health impacts, it can potentially go further in doing those kinds of things by assuring that we get that kind of information to support the policy-making process. But right now, risk assessment alone cannot answer that question. Nor does this bill, I think, right now, offer to States and to local officials that kind of answer. That's a tough policy call and I think the Federal agencies and the Congress have to make—

Mr. MCHALE. Let me ask one question, if I may. And I don't disagree with what you have just said. I don't think Dr. Ritter would either.

Don, I noticed on the closing page of your testimony you indicated that EPA and environmental policy must be reinvented, the major statutes must be addressed. This may occur incrementally through reauthorizations, but conceivably could also take place in the form of unified or organic statutes encompassing all of the individual statutes under a more multimedia market driven, less command and control aegis.

Tom Ridge, when he was a Member of the Congress, before he was elected Governor, attempted to take the principles that we're talking about here and incorporate those into a previous competitive statute on the subject of brown fields. Can the principles that we're discussing today in Title III of H.R. 9 serve as a basis, should it, Don, serve as a basis for a comprehensive statute such as that which was offered by Tom Ridge, so that we might then go forward with Brownfields reclamation?

Mr. RITTER. Well, I think if you could do it, it would be a very good idea. The only question you would have is, does this come into conflict with Safe Drinking Water Act, does it come into conflict with Clean Water Act, does it come into conflict with Superfund? And I think those would be your three major situations. That's why the issue of an organic statute that reforms the somewhat obsolete existing statutes is so important. Because you can't get to the key issues, like Brownfields, without it.

Mr. MCHALE. I thank the Chairman for his kindness. I think that conflict is inevitable. I also think that it makes sense, as you imply in your testimony, to recognize the inevitability of that conflict and resolve it in a single statutory source so that we're not going all over the board with principles that may or may not be consistent in an attempt to deal with how we clean up specific industrial sites.

Thank you very much for your kindness, Mr. Chairman.

The CHAIRMAN. Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman. I'd like to just ask the panel if they would like nod affirmatively or negatively, if I just mention a couple little points in passing. Seems to me I've heard that there is a concern about the lack of—

The CHAIRMAN. I think the reporter would prefer they answer out loud, rather than nod.

Mrs. MORELLA. I was just thinking of my five minutes of time, since we've been adhering to it, as we should. The concern I seem to hear throughout has to do with the lack of a real scientific base in the legislation, fact versus speculation. You worded it in different ways. Is that one of the concerns that you all have?

Mr. AUCHTER. Yes.

Mrs. MORELLA. They all said yes.

I also hear from you the concern, to a greater or lesser degree, about the judicial review. I think I heard several of you talk about the need to limit it. Is that a concern that you have in terms of the possible litigation without limiting judicial review in some way?

Mr. AUCHTER. Mrs. Morella, that is true that some of the panel members had that.

My view was a little bit different. I think the suggestion that I made would help to limit that administratively, which would be a petition process to the Agency head, and the petition would be based on consistency with the guidelines. And the Agency head could then conduct such a review, alter a risk assessment if required, or upon denial of such a petition, then at that stage access judicial review. So that would be a limiting factor, from my perspective.

Mrs. MORELLA. So you are talking about how it can be limited?

Mr. AUCHTER. Yes, ma'am.

Mr. YOSIE. I am not in favor of judicial review of risk assessments. I would also add that the peer review process, by definition, under the terms of the Federal Advisory Committee Act, do constitute a source of citizen petition and participation. Because citizens—these meetings are in public, they're advertised in the Federal Register, and citizens can petition the committees themselves, and Agency officials who attend those meetings, to convey their points of view.

Mrs. MORELLA. That's my third point, is the peer review process. Again, I heard the concern that, what, scientists are going to be donating their time to do this. Do we have, another question, do we have the expertise that we need in the scientific community, without draining it from other areas in order to perform an adequate peer review? Is that a concern that you all have? I see two of you would like to respond. Dr. Yosie.

Mr. YOSIE. I managed EPA's principal peer review body for about 10 years. I never encountered a situation where there was a shortage of qualified scientists and engineers in this country to participate on peer panels. I think as long as the peer review process is free of conflict of interest, I believe as long as the peer review process is geared toward scientific issues where panel members have expertise to address those issues, and I think as long as the peer review process is seen as having influence on the broader regulatory process, one would never have difficulty in recruiting qualified engineers and scientists. Members of EPA panels are com-

pensated, and their travel is paid for. So they are not losing money in the process.

Mrs. MORELLA. You wanted to comment on that?

Mr. PORTNEY. Just very briefly. I guess I want to reinforce Terry's comment. The one other thing I guess I would ask you to think about is the following, both in terms of the level of analysis that you require to and to accompany proposed regulations, and also in terms of the peer review that that analysis is subjected to, I hope the Members of the committee will try to think about a way to tailor that to the size of the problem with which you're dealing.

And what I mean by that is not every single regulation that comes out of EPA, does it make sense to conduct a million dollar benefit cost analysis or a \$500,000 benefit cost analysis. Nor does it make sense to convene a 35-person Nobel laureate peer review panel for a very small, relatively minor regulations. I think the level of analysis ought to be proportional to the economic and social and environmental significance of the regulation, and I think the peer review process should similarly be scaled up.

Mrs. MORELLA. I don't think it mentions, you know, the environmental community being involved necessarily. I think it mentions industry. Doesn't mean they couldn't be, but I don't think it's specifically noted.

Mr. PORTNEY. Sure. But I guess my point is that it's hard for me to imagine that for a significant environmental regulation that some of the expertise that you might not want on a peer review panel would reside in the environmental advocacy community, in the same way some of the expertise would in all likelihood reside in the academic community, in the business community, et cetera.

Mrs. MORELLA. Yes, Mr. McGarity.

Mr. MCGARITY. My concern is I do think you're going to run into some problems finding expertise, because things are going to change from the time that Mr. Yosie was the chairman of the—or the executive director of the Science Advisory Board. And the reason they're going to change is the thresholds are being lowered in this legislation, down to—if you go on into Title VII, that also requires the peer review, incorporates this by implication. That's a hundred people, affect on a hundred people or a million dollars. So I think you're going to see a tremendous need for peer review.

The other thing Mr. Yosie said that I think will change here, he said as long as you eliminate conflict of interest. Well, this statute particularly does not eliminate conflict of interest. It requires that it be stated at the outset, but in fact says the opposite, it says it's okay to have a conflict of interest, as long as it's stated to the Agency at the outset.

Mr. BURKE. As the former head of a Governor's Science Advisory Board, I'd like to say that perhaps it's easy for EPA, but it's not easy for all the States. Sometimes you have to multiply all their efforts by 50 to understand the magnitude of the peer review process that may be created.

Mrs. MORELLA. Do you also say that—this is the final point, the major rule, should that—should that be elevated, the threshold, to 100 million, rather than 25 million? Seems like you all agree.

Mr. AUCHTER. No, I would not agree.

Mrs. MORELLA. You would keep with the 25?

Mr. PORTNEY. It certainly should be above 1 million for a hundred people. I mean, I think it's going to bog every agency down in analysis that won't be worth it.

The CHAIRMAN. If the gentlelady would yield, your time is up. I would point out that again the only place we have any jurisdiction is in Title III, and I am told by counsel that in the peer review process in our section of the bill it's a hundred million dollars, which seems to me fits with the level that most of you would regard as being probably significant.

Mr. MCGARITY. Twenty-five million for cost benefit.

Mrs. MORELLA. Right. Thank you.

The CHAIRMAN. If you will look on page 52, for purposes of this section, the term "major rule" has the same meaning as provided in sections 3201(c), except that 100 million shall be substituted for 25 million. So in other words, what we've done is we've raised the 25 million threshold to a hundred million dollars in Title III.

Mrs. MORELLA. See, the committee has done a good job already, of pulling all the forces together. Thank you all very much.

The CHAIRMAN. Mr. Doggett.

Mr. DOGGETT. Thank you, Mr. Chairman.

I think Dr. Yosie made an important point about the conflict of interest provisions being there. And, Professor McGarity, you were just commenting on that. If I read the bill correctly, it specifically cuts out the requirements of the Federal Advisory Committee Act, and there would be no conflict of interest provision other than, what, to just state what your interest is?

Mr. MCGARITY. That's how I read it, you state what your interest is. In fact, I'm not even sure that needs to be public. It looks to me like it says you state to the Agency what the interest is.

Mr. DOGGETT. We could simply end up with these panels being people from the very—composed exclusively of consultants for the very industry being subject to regulation, couldn't we?

Mr. MCGARITY. It's certainly if the prestige of these things go down, so that academics don't particularly care to be on them, that's all that's going to be left.

Mr. DOGGETT. And since all the work is for free, they are meeting some incentive for some people who have an ax to grind to get on the peer review comments.

Mr. MCGARITY. Surely.

Mr. DOGGETT. You want to add a comment, Dr. Yosie?

Mr. YOSIE. If I may. I think a conflict of interest problem can be resolved without too much difficulty. I would suggest that two things be considered. One is that members of these peer review panels should comply with existing ethical standards that pertain to special government employees. These currently apply to peer review panel members throughout the Federal Government right now.

Secondly—

Mr. DOGGETT. Including the same standards that apply to the Federal Advisory Committee Act would do that, wouldn't it?

Mr. YOSIE. Correct, correct.

Secondly, I think there's plenty of room for participation by qualified scientists and engineers from industry, from academia, wherever. Where I become concerned is if a person on a peer re-

view panel is reviewing the data that concerns a product made or his or her company or his or her employee, I think that moves it into a conflict situation. But that need not mean that that person has to resign from the panel. That person could recuse himself or herself from that particular review, and then when the committee has moved onto the next issue, that individual can come back on the panel in a full participative way.

Mr. DOGGETT. Thank you.

Professor McGarity, as far as this problem of people being able under the bill as written to challenge in court a study upon publication before the regulation has even been promulgated, is there some specific language that you would advance to take care of that problem?

Mr. MCGARITY. Well, I suggested in my written testimony the idea that you write some language, and I could certainly work on drafting the actual language, but it would say something like judicial review is precluded or not appropriate until the time that the Agency has promulgated the final rule and the judicial review is under the arbitrary and capricious or substantial evidence test, or whatever test the statute provides for, the review of what I call substantive judicial review of the merits of the regulation.

Mr. DOGGETT. On the broader subject of the difficulty, you have expertise as both a scientist and a lawyer. Of the difficulties of lawyers and courts and judges looking at scientific questions, I'm interested particularly in this problem about how you evaluate benefits, how you evaluate, for example, the benefit of human life, how you evaluate various other qualities such as biodiversity. And what difficulties under the legislation, as it is drafted, would you expect the courts to experience in trying to audit the methods that the administrative agencies use in making those kind of calculations of the economic benefit of something that has benefit beyond economics?

Mr. MCGARITY. I think it would be very, very difficult. It's going to be difficult for the agencies do it. I've written an article just about exactly on this, on the ossification of the rulemaking process and how it gets tied up in all these analytical and judicial reviews, how both the added analytical requirements and the requirements of judicial review have just burdened the rulemaking process to the point at which it's almost unusable any more.

But the benefits themselves, there are these imponderables. Some people, I think there's a little arrogance in stating, well, this is easy. You heard testimony earlier in the week saying, well, nonsense, there's not problems, but there are problems.

In deciding whether we use a willingness to purchase tests for the benefit or a willingness to tell, the willingness to purchase test, which is mostly used in these analyses, assume that I can take it from you and you've got to buy me the right back. The willingness to sell test says I've got it and what will you pay me for it, and that can vary, depending on how valuable this is, like my life or something of that sort. Doesn't—

Mr. DOGGETT. Thank you.

The CHAIRMAN. Thank you, Mr. Doggett.

Just a couple of questions. I gather that the members of the panel generally agree, and tell me if one of you doesn't agree, that the Federal Government setting some appropriate guidelines,

overarching guidelines in this area, does in fact have a beneficial impact at the—at this juncture. Is that generally agreed by the panel?

Mr. AUCHTER. Absolutely.

The CHAIRMAN. I see everybody kind of nodding, nodding yes. And so in large part what we're doing is we're arguing about details here. They're obviously very important details, but we're arguing about kind of the principles, and then how broad that application should be.

I also gather that, at least in some instances, you believe that the most effective kind of bill will be one that has impact on very big decisions. Is that a—is that a rational position?

So in other words, if we're developing legislation here that ultimately has impact on the bigger decision that the Federal Government is rendering in the regulatory area, that will likely have also a positive effect on smaller decisions that the Federal Government also renders. Is that a logical conclusion to draw?

Mr. AUCHTER. Mr. Chairman, I think it is a logical conclusion. I don't know exactly where you're going with this, but I would suggest that the concepts that you have been hearing about in your two days of testimony, of central tendency, assessments of risk that are based on realistic outcomes, separation between what is known and what is not known, those things are absolutes and must be in the statute, I believe, that you ultimately create.

The CHAIRMAN. Let me ask you this.

Mr. AUCHTER. The small and large issue or oversight may be a place to draw lines.

The CHAIRMAN. I'm trying to figure out some parameters here in which we may be able to figure out some legislative language that in fact will have fairly broad appeal. And it's helpful. I want to make certain we don't get away from principles here that are fundamental and important. But let me ask you this. I mean, you have been fairly clear that you think the judicial review process is an important element in all of this. But I hear Mr. McGarity offering a concept here that might be able to allow us to limit the judicial review, again to kind of the big issues that arise.

Now, is—do you see major problems in placing some of those kinds of limitations to assure that judicial review, if and when it impacts the process, is on the big questions and we don't have a series of judicial reviews on fairly minor questions?

Mr. AUCHTER. I think you are right on track. When we began to discuss, as you know, we produced—the organization I am affiliated with produced a book called *Toward Common Measures*. We got this debate going and we had in mind an external review process for the process. Not as to what you would call the minutia, but it was a checklist. Boom, A, B, C, D, E—and by the time we got over to the legislative side of the equation, that had become a general review issue.

That is what I always had in mind. The judiciary would be able to review for consistency and for compliance much like the EPA.

The CHAIRMAN. There is some logic to suggest that if in fact we end up with a process where we are making a million-dollar decision that affects a handful of people, and what you end up with is

the agency in court racking up hundreds of thousands of dollars of legal fees on all sides over this thing, and that the decision then, depending on what court you are in, may actually confuse the outcome if you get a court that is not scientifically competent in all of this, that they could end up actually confusing the bigger issues that might be involved it.

Seems to me that we want to avoid that as we go through this process. And that if there is language available to us to avoid that, that we ought to consider it.

Mr. AUCHTER. Yes, sir.

The CHAIRMAN. Mr. McGarity.

Mr. MCGARITY. I can offer you an example where the court confused the process and that is the Supreme Court's decision in the OSHA benzene case where it articulated a significant risk case and then went to elaborate what a significant risk was. And it gave two examples, one of drinking a glass of water with one in a billion and breathing fumes at a gasoline station of one in a thousand risk.

If you run those through, one of course was insignificant, the court said, and the other was quite clearly significant. And if you run them through a real analysis, they are about the same. And that is a very disappointing sort of look at the competence of the courts to do this. But I think that is the Supreme Court.

The CHAIRMAN. That is a pretty revealing example.

Mr. Portney, did you have a comment?

Mr. PORTNEY. Well, yes. To give you some quantitative evidence in the spirit of the hearing, if I am not mistaken, over the past five or six years Federal regulatory agencies have dealt with proposed or final regulations numbering about 2,400 a year. Of the 2,400 regulations, about 80 are significant or major regulations given the \$100 million a year test.

I guess my point is, I would much rather focus our analytical and peer review efforts on those 80 or so major regulations and not be spending tons of money, of court time, and peer review time on a regulation that may be relatively small and which in fact often works to the benefit of the business community, the undue burdens upon which you are concerned about now.

Oftentimes they need to get something out quickly. Those tend to be the fairly minor regulations and in the spirit of prioritization about which the committee is concerned, I think we need to prioritize our analytical and peer review resources as well. And anything that you can do in that direction will make this an even better—

The CHAIRMAN. I think I am seeing amongst the panel a fair agreement with what you just said. That is indeed what we ought to try to achieve here. And I also gather, and I have been talking to counsel here, that much of what we do in Title III is in fact aimed at exactly trying to achieve that.

We may want to follow up on some of Mr. McGarity's suggestion to deal with any of the perceived problems in those areas that we may have a problem in Title VII in some of this regard. And we are already in the process of talking to the Commerce Committee and Judiciary Committee and seeing if we can't work that out it.

Sounds to me as though that is where we have got to loggerheads here and I am not certain exactly why that happened, but we will try to resolve some of those issues.

Mr. BROWN. If you are through, Mr. Chairman, I wanted to make a final comment for the benefit of history.

Mr. Burke, you coined a new phrase of dueling risk assessments. And I wanted you to know in the first hearing on risk assessments, which I participated in in the spring of 1960, the dueling risk assessments were presented very, very vividly. This was a hearing on the potential health effects of ambient lead and we had testimony which indicated that a little bit of ambient lead really contributed to a good and healthy long life. And then we had other testimony on the other side which said it might be dangerous to your health. I want the record to reflect that.

The CHAIRMAN. I thank the gentleman.

I thank the panel very much. It has been very helpful and we appreciate your spending some time with us and giving us the benefit of your views.

With that, this hearing stands adjourned.

[Whereupon, at 4:09 p.m., the committee was adjourned.]





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